A COMPARATIVE STUDY OF CONVENTIONAL TONSILLECTOMY VERSUS COBLATION TONSILLECTOMY

Dissertation submitted to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfilment of the regulations for the award of the degree of

M.S. OTORHINOLARYNGOLOGY

BRANCH – IV

DEPARTMENT OF OTORHINOLARYNGOLOGY

KILPAUK MEDICAL COLLEGE CHENNAI - 600 010.

APRIL - 2016

CERTIFICATE

This is to certify that **Dr. A. BALAKRISHNAN,** postgraduate student (2014 – 2016) in the Department of Otorhinolaryngology, Government Kilpauk Medical College and Hospital, Chennai has done this dissertation titled **"A COMPARATIVE STUDY OF CONVENTIONAL TONSILLECTOMY VERSUS COBLATION TONSILLECTOMY"** under the direct guidance and supervision in partial fulfillment of the regulations laid down by the Tamil Nadu **Dr. M.G.R. Medical University, Chennai, for M.S.Branch–IV Otorhinolaryngology Degree Examination.**

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DECLARATION

I **Dr. A. BALAKRISHNAN** solemnly declare that the dissertation titled **"A COMPARATIVE STUDY OF CONVENTIONAL TONSILLECTOMY VERSUS COBLATION TONSILLECTOMY"** is a bonafide work done by me at Government Kilpauk Medical College under the guidance and Supervision of **Prof. Dr. P. ILANGOVAN MS, DLO.,** Professor of Otorhinolaryngology.

This dissertation is submitted to the **Tamil Nadu Dr. M.G.R. Medical University** towards the partial fulfillment of the requirements of M.S. Branch – IV, Otorhinolaryngology degree examination.

Chennai

Date : **Dr. A. BALAKRISHNAN**

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INSTITUTIONAL ETHICAL COMMITTEE
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CERTIFICATE OF APPROVAL

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The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

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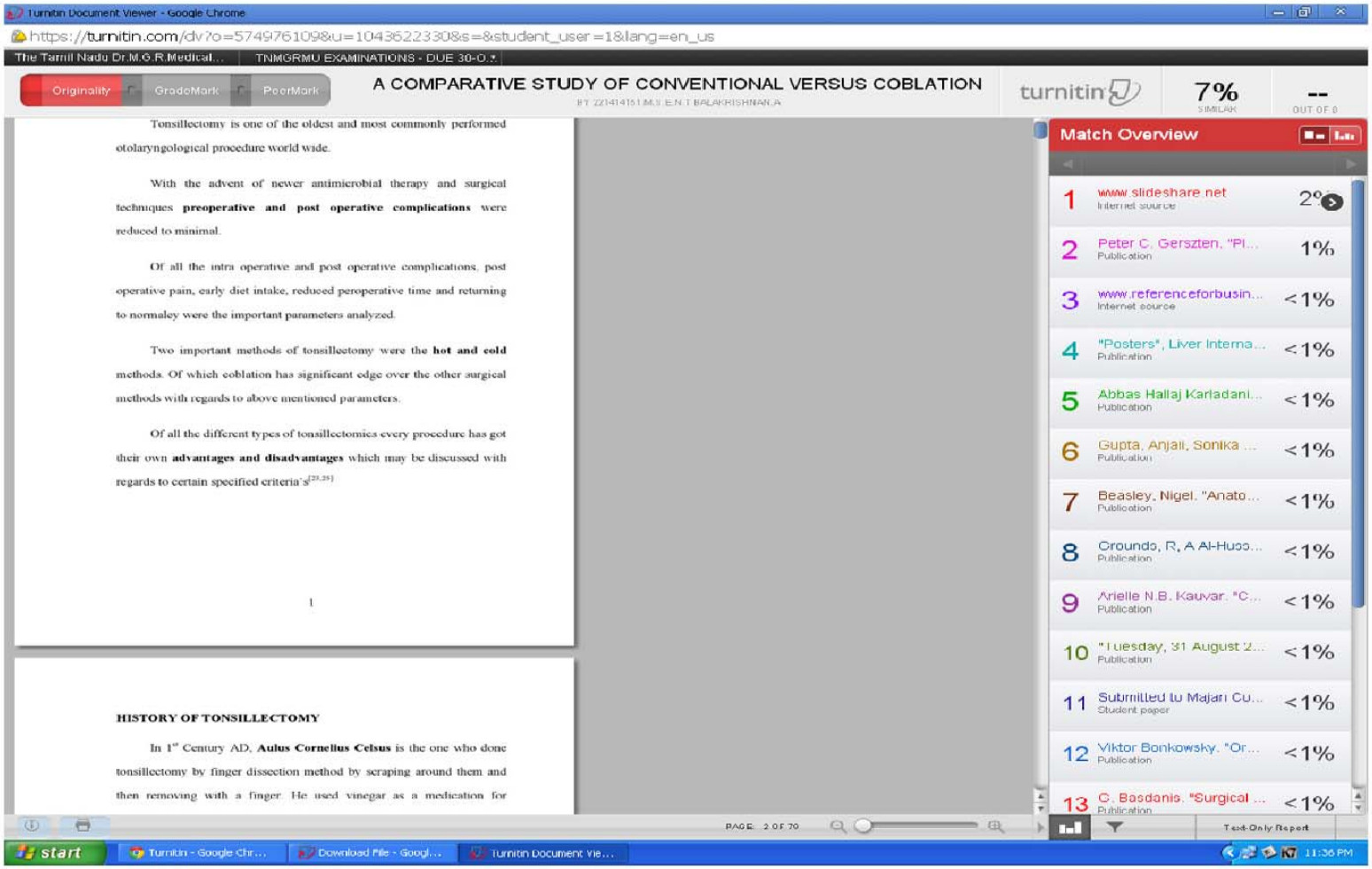
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With the advent of newer antimicrobial therapy and surgical techniques preoperative and post operative complications were reduced to minimal.
Of all the intra operative and post operative complications, post operative pain, early diet intake, reduced peroperative time and returning to normaley were the important parameters analyzed.
Two important methods of tonsillectomy were the hot and cold methods. Of which coblation has significant edge over the other surgical methods with regards to above mentioned parameters.
Of all the different types of tonsillectomies every procedure has got their own advantages and disadvantages which may be discussed with regards to certain specified criteria's[23,25]
1
HISTORY OF TONSILLECTOMY
In 1st Century AD, Aulus Cornelius Celsus is the one who done tonsillectomy by finger dissection method by scraping around them and then removing with a finger. He used vinegar as a medication for
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INTRODUCTION

Tonsillectomy is one of the oldest and most commonly performed otolaryngological procedure world wide.

With the advent of newer antimicrobial therapy and surgical techniques **preoperative and post operative complications** were reduced to minimal.

Of all the intra operative and post operative complications, post operative pain, early diet intake, reduced peroperative time and returning to normalcy were the important parameters analyzed.

Two important methods of tonsillectomy were the **hot and cold** methods. Of which coblation has significant edge over the other surgical methods with regards to above mentioned parameters.

Of all the different types of tonsillectomies every procedure has got their own **advantages and disadvantages** which may be discussed with regards to curtain specified criteria's[29,39]

1

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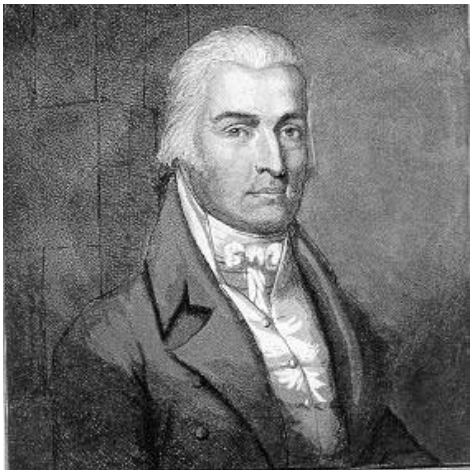
HISTORY OF TONSILLECTOMY

In 1st Century AD, **Aulus Cornelius Celsus** is the one who done tonsillectomy by finger dissection method by scraping around them and then removing with a finger. He used vinegar as a medication for postoperative hemostasis.

In 6th Century AD **Aetius of Amida** introduced Hook and knife method. **Philip Syng Physick** was the first to develop the tonsillotome. He was known as "Father of American surgery"[3,5]



In late 1800s **Mackenzie** was one who made tonsillotome used commonly.

Tonsil removal can be done either by Partial or by complete method.

William Lincoln Ballenger was the one who did complete removal of tonsil with the intact capsule in 1906.

George Ernest Waugh was the first to describe complete tonsillectomy in1909.

During 1911-1917 **Crowe** did 1000 tonsillectomies using Crowe-Davis Mouth gag by Sharp dissection method.

Guillotine method- is an obsolete and outdated method, where tonsil was displaced medially by digital pressure and fenesterated through the instrument and the tonsil amputated by closing the guillotine blade, with the major disadvantage of incompletely removed tonsil. It is an non dissection method.

Different techniques of tonsillectomy

Dissection Method

Dissection and snare method

Electro sterlisation of tonsils

Monopolar Diathermy

Bipolar Diathermy

Laser tonsillectomy - Carbon di oxide

Potassium titanyl phosphate

Nd-yag laser

Ultrasonic dissection

Harmonic scalpel dissection

Power assisted tonsillectomy

Cryogenic tonsillectomy

Radio frequency /electro surgery

Coblation tonsillectomy

HISTORY OF COBLATION

Sunnyvale in California discovered coblation based products use radiofrequency energy to dissolve soft tissue without burning, unlike other radiofrequency based products, like laser, that are heat driven. Initially coblation was used in sports medicine. Arthowands repairing the shoulders and knees ligaments injury.

Coblation technology recently leverages better performance of tonsillectomies and also for other procedures for snoring and nasal symptoms. The coblation unit also represents cosmetic wrinkle free surgical technique.[1,12,15]

So invention of coblation can revolutionized ENT surgical techniques with better precision and positive outcomes which may be enabled in future for other invasive procedures such as skull base surgery and temporal pathology

Coblation technique was apparent that this technique held great promise offered to the surgeons, with the traditional electrosurgical instruments and lasers.

Our study aims at comparing conventional method (**dissection and snare method)** with **coblation method.** **[72,74,75]**

PALATINE TONSIL

Palatine tonsils are dense, compact bodies of lymphoid tissue located in the oropharynx. Tonsil presents varying appearance in different subjects or in the same subject at successive ages[1, 21].

EMBRYOLOGY

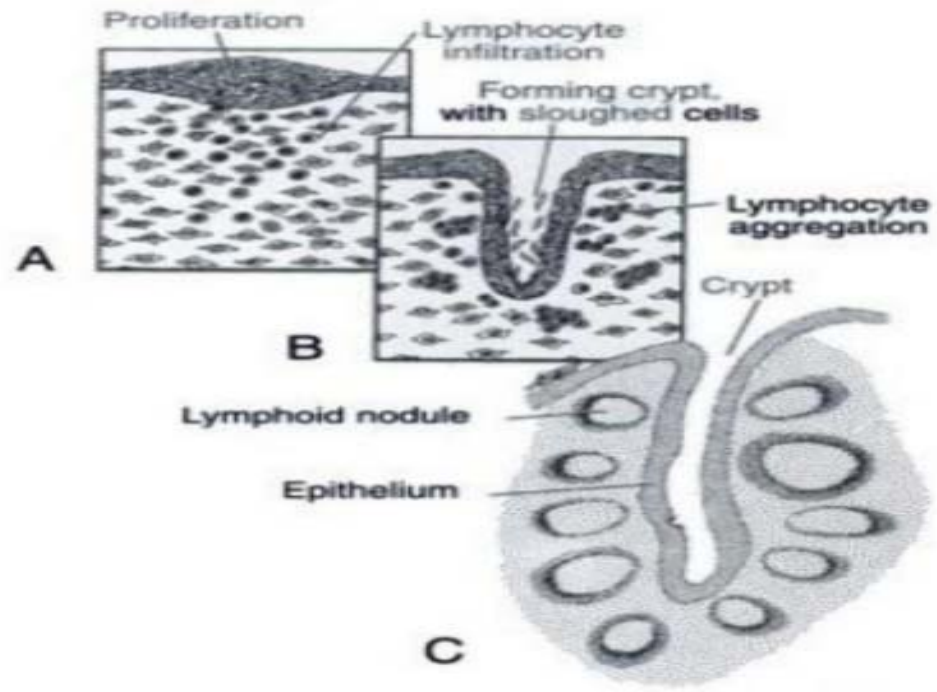
The tonisillar pillars are formed from 2nd and 3rd branchial arches, through dorsal extension of mesenchyme forming soft palate.

Tonsillar crypts are developed on 3-6 months of intrauterine life as a solid in growth from surface epithelium. They branch, rebranch and even regress after birth. Intratonsillar cleft represent remaining of second pharyngeal pouch.[1,2]

Lymphocytes appear near the epithelium during 3rd month but organize to nodular form after 6th months.

By 5th month, the tonsilar capsule is formed by mesenchyme.[6]

The upper part of the tonsil which passes deep to the plica semilunaris and extend in to soft palate.



SITUATION :

Tonsil is situated in the oropharynx in the **tosillar fossa** bounded by palatoglossal and palato pharyngeal folds. [1,24,45,]

STRUCTURE:

Tonsil is an almond shaped mass of specialized sub epithelial lymphoid tissue, that has Two surfaces.

Medial

Lateral

Two poles Upper pole

Lower pole

UPPER POLE – almost free extends in to soft palate anteriorly. A semilunar fold covering the tonsillar space in between is known as **supratonsillar fossa** [1,15,18]

LOWER POLE – Embedded besides the base of tongue. A triangular fold which forms plica triangularis and attached to the tonsil is known as **tonsillo lingual sulcu**s through which tonsillar artery enters the tonsil Lymphoid tissue is continuous with the subepithelial lymphoid tissue on base of tongue called **lingual tonsil**

MEDIAL SURFACE - 15 to 20 opening of tonsillar crypts are irregularly placed over the surface. Crypts and medial surface of tonsil are lined by stratified squamous non- keratinized epithelium.

LATERAL SURFACE : Lined by a capsule. Deep part of tonsil is separated from the wall of or pharynx by loose areolar tissue. Well defined fibrous tonsillar micapsule is formed by condensation of the **pharyngobasillar fascia.** **[56,57]**

Loose areolar tissue lies between the capsule and bed of tonsil.

Palatine vein/external palatine/paratonsillar vein descends from the palate in the loose areolar tissue.(1,21)

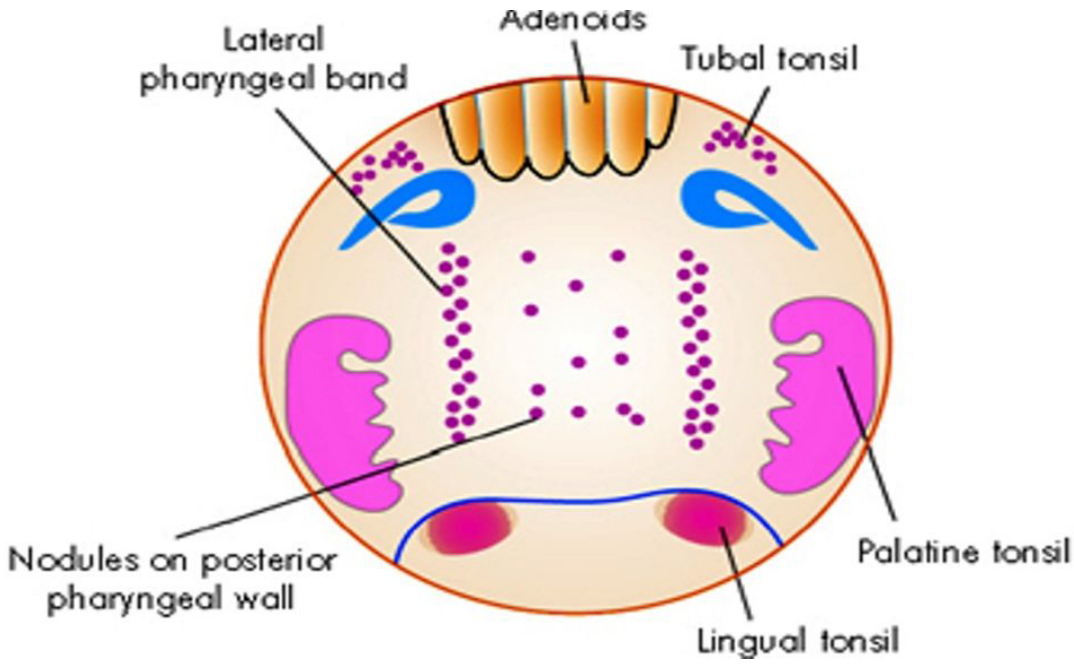
The capsule is firmly attached anteroinferiorly to the side of the tongue, just in front of the insertion of **palatoglossu**s and **palatopharyngeus** muscles.

Tonsillar artery enters near this firm attachment.

The fascia extends into the tonsils forming septa for passage of vessels and nerves.

Waldeyer's ring

A group of lymphactic organs guarding the oropharynx and nasopharynx in the forum of the ring. the ring is bounded above by pharyngeal tonsil and tubal tonsil below by lingual tonsil and left and right side by palantine tonsils and lateral pharyngeal bands.[1,17,21]



TONSILAR BED:[1,13,15]

formed by the following structures from medial to lateral

loose areolar tissue with paratonsillar vein

pharyngobasilar fascia

superior constrictor- superiorly

buccopharyngeal fascia

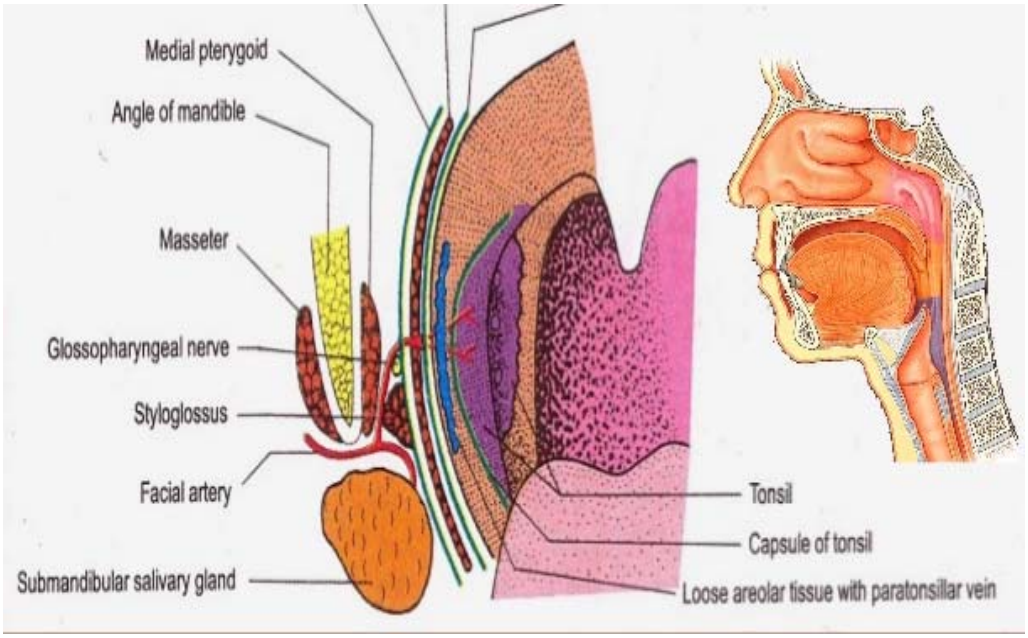
styloglossus- inferiorly

medial pterygoid muscle

glossopharyngeal nerve

stylohyoid ligament

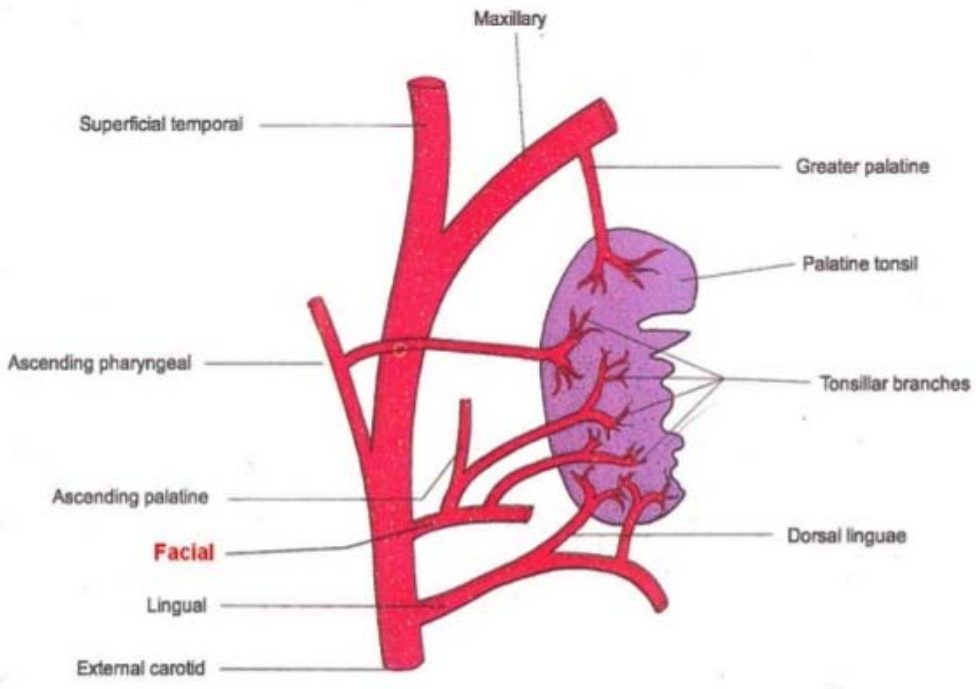
internal carotid artery



BLOOD SUPPLY:

Blood supply for the palatine tonsil is from 5 arteries :

- Tonsillar Branch of Facial Artery
- Ascending palatine branch of facial artery
- Ascending pharyngeal branch of external carotid artery
- Dorsal lingual branch of lingual artery
- Desending palatine artery from maxillary artery



NERVE SUPPLY :

Sensory Supply - Tonsillar branch of glossopharyngeal nerve

Upper part of tonsil near soft palate receives **Lesser palatine branch** of maxillary division of trigeminal nerve through the ptergopalatine ganglion.

Lymphatic drainage: No afferent lymphatics

Tonsillar fossa – upper deep cervical nodes

Anterior pillar- Upper deep nodes along the internal jugular vein and sub maxillary group of nodes and rarely into posterior triangle nodes.

P**osterior pillar** – Upper deep cervical nodes , posterior triangle nodes along spinal accessory nerve.

Lingual tonsil: Revised papilliform masses in posterior 1/3 tongue.

Each mass has a single opening on mucosal surface that form tubular gland and crypts.

Lined by **squamous epithelium.**

HISTOLOGY:

Oral aspect – Non-keratininzing stratified squamous epithelium

Crypts greatly increase the contact surface – 295 cm^2

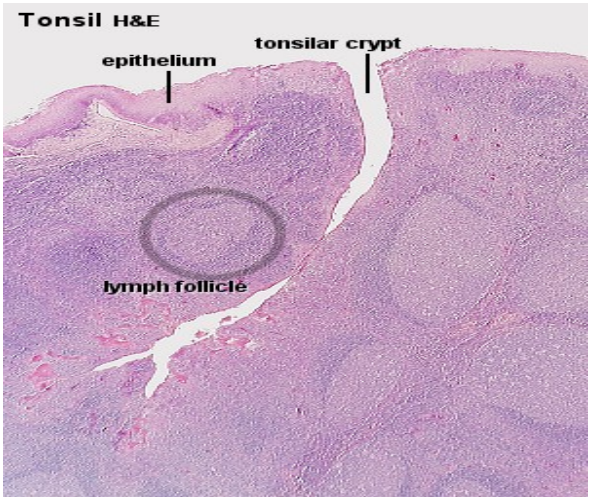
4 lymphoid conpartments within the tonsil are

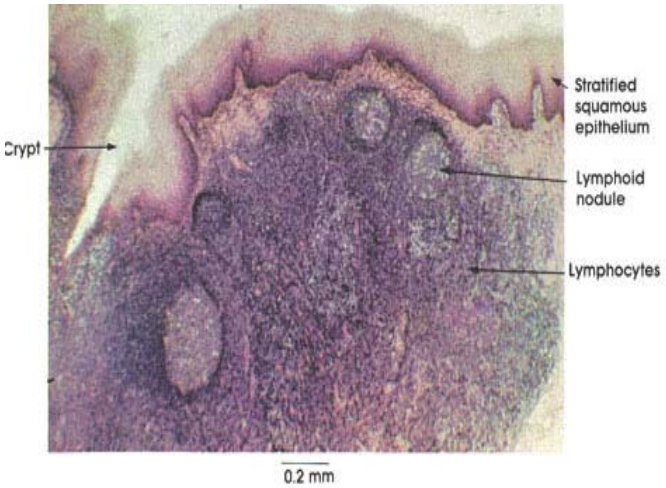
– Reticular cell/crypt epithelium

– Extrafollicular area

– Mantle zone of lymhoid follicle

– Germinal centre of lymphoid follicle





- The free oropharyngeal surface is lined by stratified squamous non-keratinized epithelium
- In the underlying lamina propria, simple and branched epithelium crypts are present representing tubular invaginations of surface epithelium
- Between crypts, masses of lymphoid tissue containing numerous individual lymphoid nodules are present.

FUNCTIONS OF TONSIL:

Palatine tonsils have a protective role acting as sentinals at the portal of air and food passage.

Tonsils are large in childhood and diminish in size near puberty.[1,57,68]

Secondary lymphoid organ of predominantly of B-cell type Antigen uptake. Weak antigenic stimulus: differentiation of lymphocytes to plasma cells. Strong antigenic stimulus: proliferation of B-cells in germinal centres.

Most active: 4-10 years of age

PATHOPHYSIOLOGY OF TONSILLITIS:

ACUTE TONSILITIS: Acute inflammation of tonsil usually seen in children or adolescents.

DIFFERENT TYPES : [1,45,56,72]

Acute catarrhal: Tonsillitis as a part of the generalized Pharyngitis Mostly caused by virus where the whole tonsil is congested.

Acute Follicular Tonsillitis : Infection spread into crypts which become filled with purulent material, presenting at the opening of crypts as yellowish spots.

Acute parenchymatous: Substances of tonsil so whole of tonsil is congested and uniformly enlarged.

Acute membranous: It is a stage ahead of follicular tonsillitis when exudation from the crypts coalesces to form a membrane on the tonsillar surface.

AETIOLOGY: Commonest are bacterial and viral

Viral	**Bacterial**
Adenovirus	Group A **Beta** haemolytic streptococci
Rhinovirus	Staphylococci
Parainfluenza virus	Pnemococci
Influenza virus	Hemophilus influenza
Enterovirus	
Epstein Bar Virus	

Bacteria

Staphylococci: [1,56]

Gram positive cocci they are arranged in pairs of short chains irregular grape like structure non motile facultative aerobe dividing along the different planes and the daughter cells attach to one other.

Virulence factors for staphylococcus aureus are exotoxins A and B

Pneumococci:

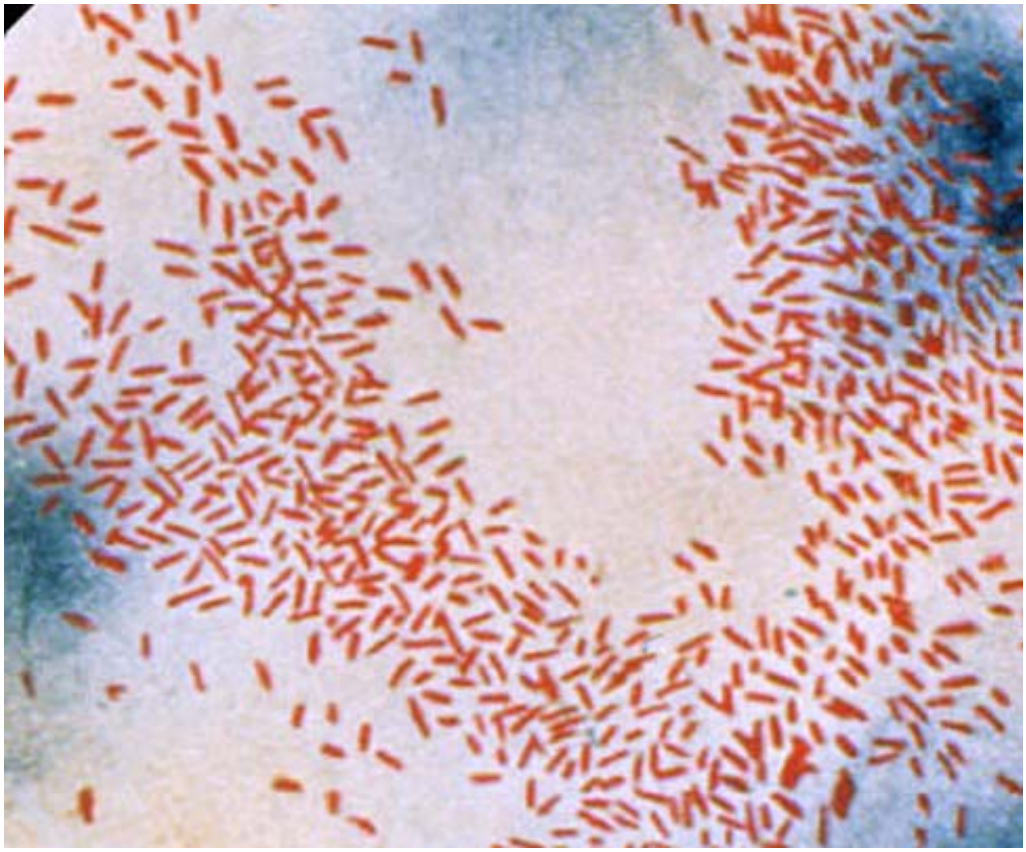
Gram positive Lancet shaped diplococcic arranged in short chains with capsule

Hemophilus influenzae [22,31]

Also called as **Pfeiffer' s Bacillus** , it was first described in influenza pandemic in 1892.

Small non motile gram negative rods which is a normal flora of human respiratory tract.With a polysaccharide capsule.95% of invasive disease are caused by t**ype B**.

It is one of the most common invasive infection. Usually in the host, it presents without causing any disease, following viral infection, reduced immune function and allergies create an oppurtunity striking the host cell by **trimeic auto transporters adhesions**



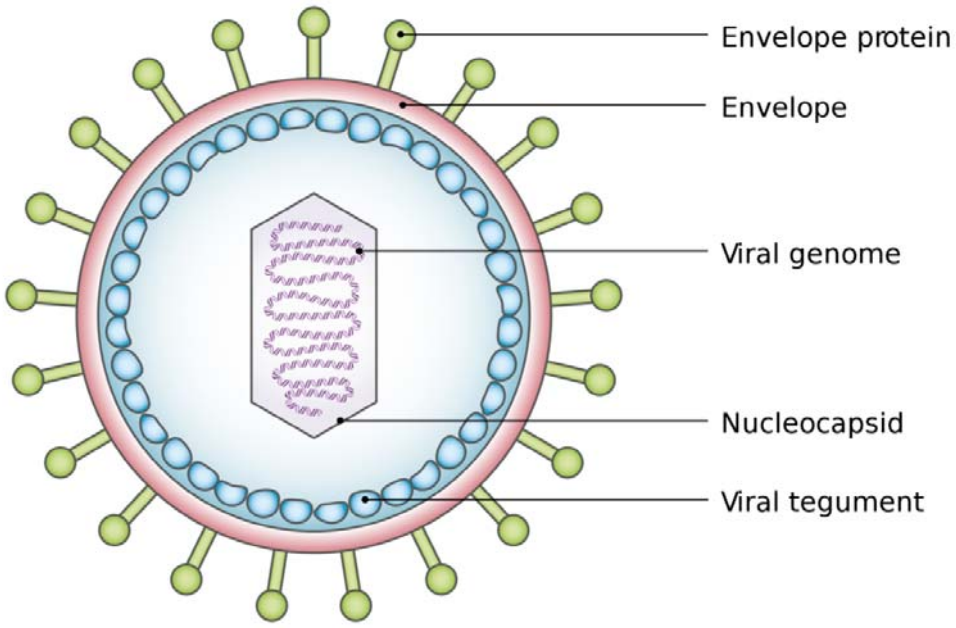
Infectious mononucleosis; [23,25]

This affect young adults both tonsil are very much enlarged, coverd with Membrane, lymph nods are enlarged in the posterior triangle of neck along with **hepatosplenomegaly**.

Blood smear shows more than **50%** of lymphocytes of which **10% are atypical**.

Paul bunnell test will show high titre of hetrero phile antibody.

Ebstein barr virus



Usually the symptoms occur after following 4-6 wks of infection.

RHINO VIRUS : [1’13]

Single stranded RNA virus.

The most common upper respiratory infection caused by the rhino virus.

Method of transmission:

Aerosal

Person to person by direct contact

Rhino virus containing four viral protein VP -1, VP -2, VP-3 VP-4.

ADENO VIRUS: [11,12]

It is an non enveloped, double DNA virus. Name derived from human adenoids in 1953.

They are able to transported through the endosome.

RECEPTORS:

CD-46

COXSACKIE VIRUS ADENOVIRUS RECEPTOR (CAR)

After the virus entering the cell, the endosomes acidifies leads to capsid components to disband. With cellular microtubules, adeno virus enter the nucleo pore complex by transmission.

SYMPTOMS:

The predominant symptoms are

- Sore throat,
- Difficulty in swallowing
- Fever
- Earache
- Headache, malaise, h/o of repeated attack of tonsillitis

SIGNS:

Foul breath, coated tongue

Hyperemia of pillar, soft palate, uvula

Tonsils are congested swollen with yellowish spots/membrane

Jugulodiagastric nodes are enlarged and tender.

TREATMENT:

Bed rest, plenty of fluids

Analgesic and antipyretics

Local antiseptic mouth gargles

Antibiotics

ANTIBIOTICS: [56,58,62]

Before starting antibiotics ,

Throat swab

Blood investigations (**ASO titre**)

After confirming the type of organism, start the appropriate antibiotics

FIRST LINE THERAPHY:

Oral pencillin group of drugs advised for 10 – 14 days

Cephalosporins group can given orally for 10 days

MACROCLIDES:

Allergic to pencillin groups of drugs

Erythromycin

Clarithromycin

Azithromycin

In resistant cases, not responding to single line of theraphy, combination of drugs can be used.

Amoxycillin + clavulinic acid

I.V antibiotics are advised in suspected complications.

ANTO STREPTOLYSIN – 'O' TITRE (ASO)

It is an blood test that measures **antibodies against streptolysin O** that the substance produced by Group A streptococcus.

Normally the value less than 166 todd units or less trhan 200 International units known as the **negative test**.

If it is more than 166 todd units or more than **200** International units, known as **positive test.**

It indicates a recently infected by Group A, C , G streptococci, following upper respiratory tract infection, **scarlet fever**, **toxic shock syndrome**.[33,35]

Also used an post streptococcal infection causing complications,like **glomerulonephritis and Rheumatic fever**.

But, the test positive in **80 – 85 %** of acute streptococcal infection. If it is negative , it doesnot ruleout , infection not due to streptococcus.

The antibodies level usually starts to rise at **1-3 weeks** following upper respiratory tract infection due to streptococcal infection. The level peaks at **3 – 5 weeks** and it goes insignificant level in blood at **6-12 months.**

COMPLICATIONS:

Chronic tonsillitis with recurrent acute attacks.

Peritonsillar abscess

Paraphyrangeal abscess

Acute otitis media

Rheumatic fever,

Acute glomerulonephritis,

Subacute bacterial endocarditis.

PERITONSILLAR ABSCESS:

Following tonsillitis collection of pus in the Peritonsillar space known as peritonsillar abscess or Quinsy's disease. Commonly occur one side of the tonsil.

Symptom : severe pain in affected side

Fever

Difficulty in swallowing

Painful swallowing

Not able to swallow saliva also

Not able to open the mouth also

Treatment

Incision and Drainage - incision made in superior pole and anterior pillar junction let out pus under local anaesthesia.

Antibiotic for 1 to 2weeks till the symptoms subsides.

Interval Tonsillectomy

Tonsillectomy should be done after 4-6 weeks following attack of peritonsillar abscess.

Hot Tonsillectomy:

It is the one even in peritonsillar abscess, in this surgery bleeding will be more and secondary infection also common.

Differential diagnosis of membranous tonsillitis: [1,37,39,40]

Membranous tonsillitis: due to acute infection exudative membrane forms the medial surface of tonsil ,with congestion of anterior pillars, uvula, soft palate.

Diphtheria

Vincent angina

Infectious mononucleosis:

Agranulocytosis

Leukaemia

Aphthous ulcers

Malignancy tonsil:

Traumatic ulcer

Candidal infection

1.

CHRONIC TONSILITIS:[1,37,39,40]

Chronic inflammation of the tonsils which usually starts following acute inflammation. Crypts of inflames tonsils are filled with organism and chronic inflammatory cells, exudates and debris.

Lining epithelium gets **denuded**, minute abscess walled off by chronic inflammatory cells present in parenchyma. Reduction of barrier functions including production of **immunoglobulin A.**

SYMPTOMS:

Repeated attacks of sore throat with little remission in between chronic throat irritatation and cough

Difficulty in swallowing

Pain around the neck

Fever

Halitosis

Breathing problem

Snoring

CLINICAL TYPES BASED ON EXAMINATION

Chronic parenchymatous: Tonsils are uniformly enlarged and congested.

Chronic follicular: Beads of whitish yellow discharge on the surface at the entry of crypts

Chronic fibroid: Tonsils are small but pressure on anterior pillar exudes cheesy material

CARDINAL SIGNS OF CHRONIC TONSILLITIS [41,44]

Hypertrophied or atrophied tonsils

Anterior pillar congestion

Extrusion of cheesy material on pressure over anterior pillar with two tongue depressors **(squeeze test/ Irwin Moore sign)**

Enlarged, non tender jugulodiagastric nodes

TREATMENT:

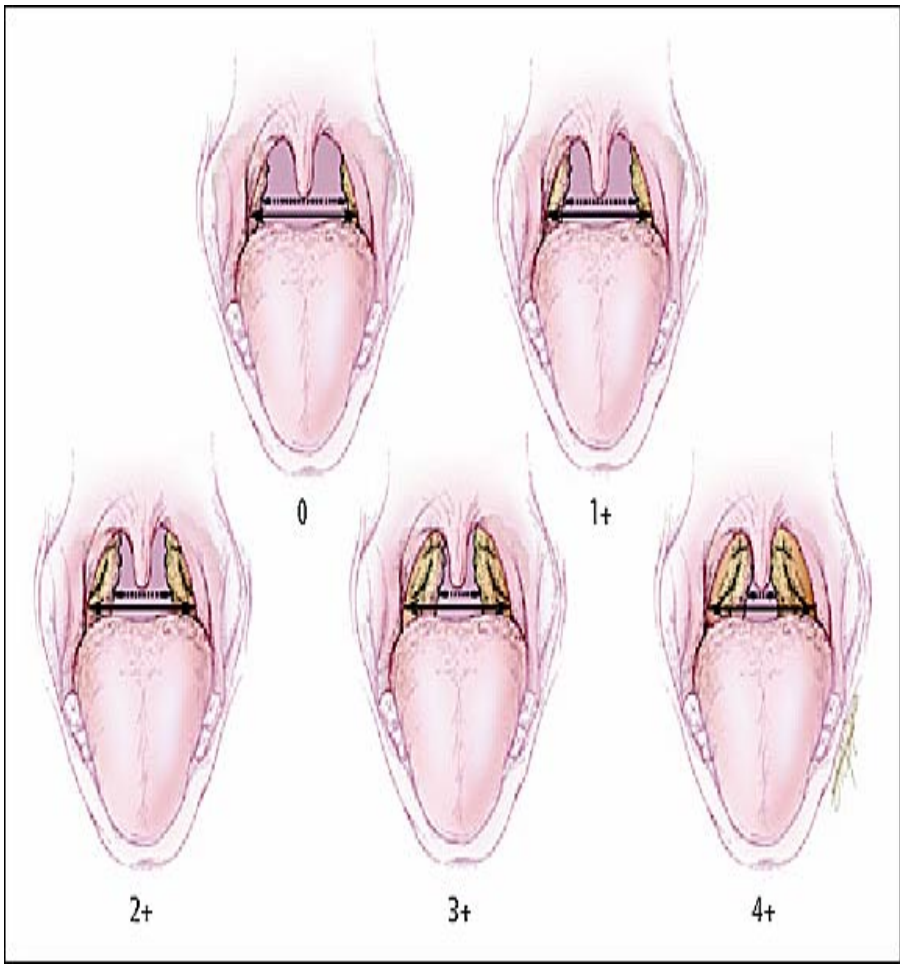
Initially conservative with **antibiotics**, analgesics and bed rest

In chronic recurrent infections, tonsillectomy is indicated

CHRONIC TONSILLITIS GRADE 3 HYPERTROPHY

CHRONIC TONSILLITIS WITH GRADE 3 HYPERTROPHY

WITH OUT ADENOIDS



GRADES OF CHRONIC TONSILLITIS

GRADE 1 - Less than 25% within the tonsillar fossa

GRADE 2- 25% to 50% up to tonsillar pillar

GRADE 3- 50 to 75% beyond the pillars

GRADE 4- More than 75% kissing each other

INDICATIONS FOR TONSILLECTOMY

Absolute indications:[1,13,15]

Recurrent attacks of acute tonsillitis (more than **6** episodes per year in young child or **2-3** episodes per year for several years)

Chronic tonsillitis

Interval tonsillectomy following peritonsillar abscess.

Focal infection of ear like Chronic suppurative otitis media.

Part of sleep apnea syndrome(enlarged tonsil)

Tonsillolith

Benign tumours of tonsil(papilloma)

Suspected malignancy of tonsil.

Relative indications: [1,15,17]

Rheumatic heart disease

Acute glomerulonephritis.

Failure to thrive.

Dermatological indications –where tonsils are taught to be a septic focus.

EPIDEMIOLOGY

Tonsillectomy was one of the most common surgery performed, since ancient time to the 21st century

Most common surgical procedures performed in children as well as in adult in the United States and European countries asian countries.

In 1959, nearly about **1.4 million** tonsillectomies were done in the United States. This number had dropped to **250,000** by 1987 due to development of modern antibiotics even though tonsillectomy is one of the most common surgery done in our for chronic tonsillitis , focal sepsis and a part of sleep apnoa syndrome surgery.

The tonsillectomy was done in the hospital admission shows **24th** most common surgery in the world wide.

ADVANTAGES OF TONSILLECTOMY: [23,34,35]

Less use of antibiotics

Avoid devepoment of resistance to antibiotics

Prevention of recurrent episodes

Prevention of spread from focal sepsis

Partial correction of obstructive symptoms

DISADVANTAGES OF TONSILLECTOMY: [31,34,37]

Alteration of Immunity in less than 12 years

Hyper nasal speech due to - Injury to soft palate

Blood transfusion – depends on blood loss

Aspiration

Risk of mortality is 1 in 2,50,000

CONVENTIONAL TONSILLECTOMY

DISSECTION AND SNARE: [1,38,72,74]

Under **General anaesthesia**, with cuffed endotracheal tube into the trachea, using Boyle davis mouth gag, mouth was opened, using tonsil holding valsellum, tonsil retracted medially.

Using **waugh's** toothed forceps, incision made in anterior pillar and superior pole junction ,through which tonsil was dissected from superior pole to inferior pole using tonsillar dissector.

In the inferior pedicle is snared using Eve's tonsillar snare , tonsil was crushed and removed. Bleeding sites were identified and ligated.

The usage of **Eves tonsillar snare** was to crush the pedicle with the release of **tissue thromboplastin** which **converts prothrombin to thromb**in which in turn converts fibrinogen to fibrin thereby activating the external clotting mechanisms.

During the procedure the amount of blood loss was calculated from both the suction and previously weighed cotton balls.

Time noted since using Boyle davis mouth gag and removal of both tonsils achieving hemostasis.

INSTRUMENTS USED IN TONSILLECTOMY

Boyle davis mouth gag with tongue blade

Dennis browne tonsil holding valsellum

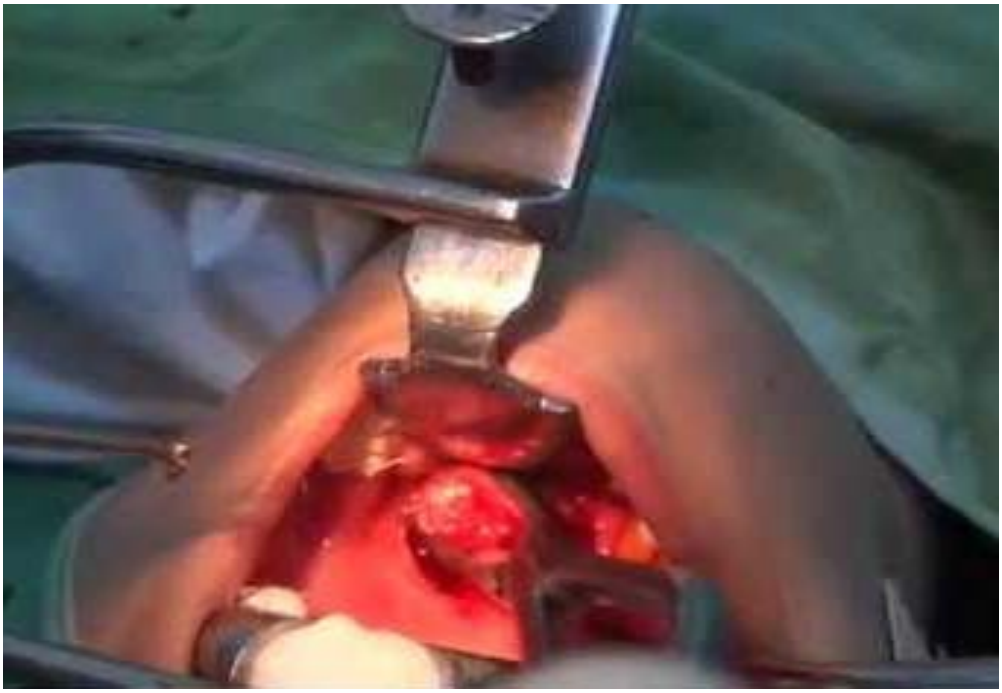
Mollison’s anterior pillar retractor and tonsil dissector

Eve’s tonsillar snare

Yankauer’s suction tube

Negus knot tier

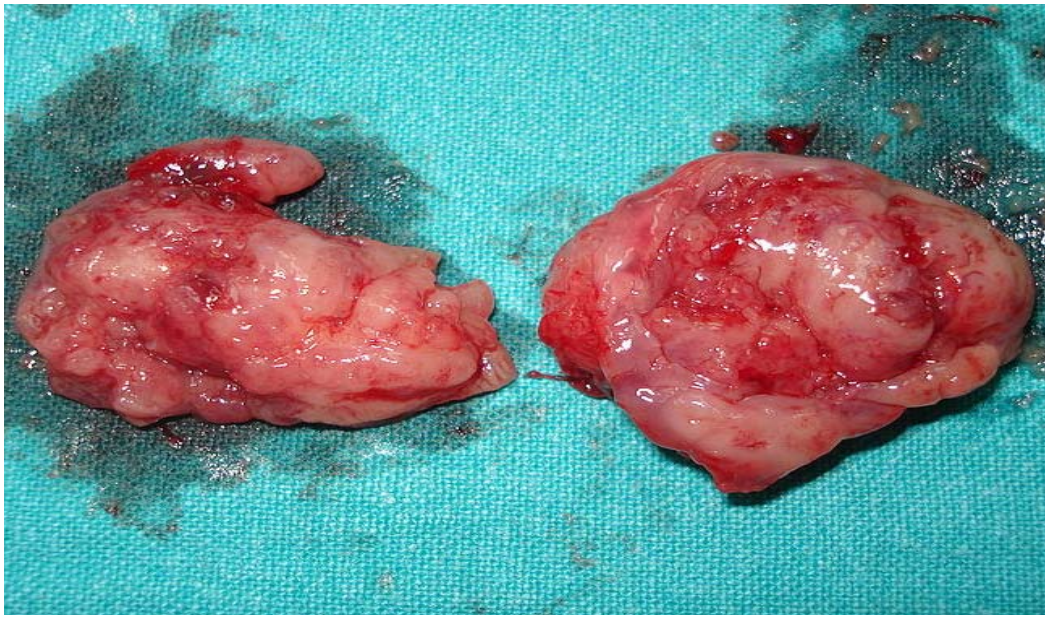
Conventional method of tonsillectomy by Dissection and snare method



Using Eves tonsillar snare the inferior pedicle was snared

SPECIMEN OBTAINED USING CONVENTIONAL

TONSILLECTOMY



Post operative day 2

Tonsil fossa –free, healthy slough covered fossa

COBLATION TONSILLECTOMY

Definition:

Surgical procedure done using microscope under general anaesthesia with controlled ablation of dissociating tissue using a **plasma based radio frequency** (RF) device with removal of **defined volume of tissue** (ablation) or passing high frequency of current with **denaturation of tissue protein** and collagen (tissue coagulation), breaks molecular bonds excising or dissolving soft tisssues at relatively low temperature typically **40 degree c to 70degree** c thereby preserving the **integrity of surrounding healthy tissue and subsequent hemostasis** using specialized coblation wands.[1,74,75,76]

After arranging the coblation with microscope, intra operative time is calculated from the time of boyle davis gag application to the removal of both tonsil from tonsillar fossa.

During the procedure the amount of blood loss was calculated from both the Suction apparatus and previously weighed cotton balls with fully blood soaked cotton balls taking weight in to consideration.

Each fully soaked cotton balls weighs 2 ml of approximated blood value. The amount of blood loss is calculated from blood soaked cotton balls X NO of cotton balls used.

Coblation settings:

Coblation technology works by generating a electric field between a single electrode or a cluster of active electrodes located on the tip of RF device.

Current flows through an electrically **conductive medium** such as **saline**. Voltage of 150- 250 volts were introduced across the electrodes on a wand creating a high density energy field called plasma. The coblation wands used radio frequency excitation of frequencies ranging from **100 to 500 KHz.**

Within the the electric field ,current density exceeds the heat of vaporization of fluid and dissipates due to thermal conduction increasing the electrical field of around 300 volts fragmenting the water molecules and plasma. [7,77,78]

In this manner target tissue is effectively dissolved or volatilized in a low temperature with a minimal or no damage to surrounding tissue.

Commonest surgeries using coblation in ENT

Tonsillectomy

Adenoidectomy

Turbinectomy during nasal surgeries

Uvulo palate pharyngoplasty

Tongue base reductions

Laryngeal polypectomy

Resection of benign tumors of larynx, hypo pharynx, oral cavity and oropharynx

Creating a cavity in a malignant lesion

COBLATION SYSTEM

CONTENTS:

Wand with electrode configuration (wand—evac-70)

Voltage controller setting

Impedance (surface area controlling system)

Coagulation controlling system

COBLATION METHOD OF TONSILLECTOMY USING

MICROSCOPE UNDER GENERAL ANAESTHESIA

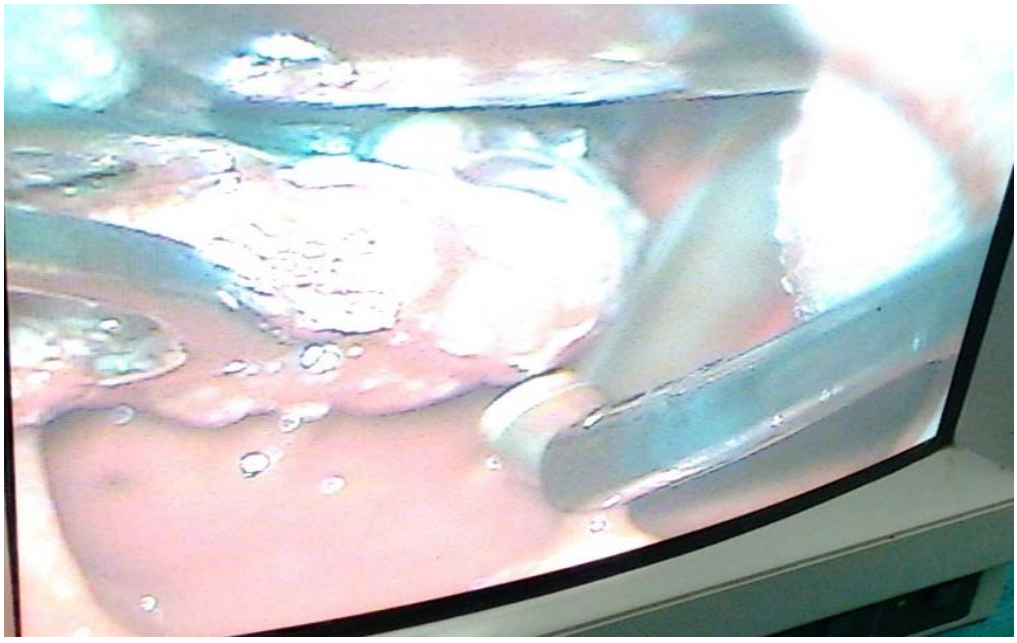
Microscopic assisted TV Monitoring coblation

Tonsillectomy was done

With E- VAC 70 Tonsillar wand

COBLATION TONSILLECTOMY

Using tonsillar wand tonsil being removed by controlled ablation method.



Under microscopy with TVmonitor shows tonsil removed by controlled ablation method in our hospital

COMPLICATIONS OF TONSILLECTOMY

Immediate

1. Primary Haemorrhage

Haemorrhage during the surgical procedure from the onset to end of the surgical procedure. It can be controlled by pressure ligation electo coagulation of bleeding vessels

2. Reactionary haemorrhage –within 24hours after the surgical procedure mainly due to slippage of knot. Controlled by removal of clot, application of pressure, vasoconstrictors if not controlled proceed to ligation or electro coagulation

3. Surgical truma –tonsillar pillars,uvula ,soft palate, tooth
4. Aspiration of blood
5. Facial edema
6. Surgical emphysema

Delayed complications

Secondary haemorrhage after 24 hours of the surgical procedure usually 5^{th} to 10^{th} post operative day due sepsis and premature separation of the membrane.control by removal of clot, tropical application of hydrogen peroxide and systemic antibiotics.

Lung complication –due to aspiration of blood mucous or tissue fragments

POST OPERATIVE CARE

Immediate general care

Patient was kept **in lateral position** on his sides with knees and limbs in flexion, to facilitate removal of secretions from mouth and throat

Bleeding from the mouth was watched for

vital signs (HR,RR and BP) were checked

Diet

After full recover from anaesthesia **, cold milk or ice cream** was given to the patient

Sucking of ice cube gives relief from pain

Diet was gradually changed from soft to solid food.

Plenty of fluids was encouraged

Diet to be avoided -

Hot and spicy food

Carbonated drinks

Preserved foods

Patient was monitored for **Next 3 Days**

SECOND POST OPERATIVE DAY FOLLOWING

Coblation tonsillectomy showing healthy tonsillar fossa

Both Tonsils were removed by Coblation method shows complete removal of both tonsils with healthy slough covering tonsillar fossa in our hospital.

AIM OF THE STUDY

To compare and study the advantages of conventional (Dissection and snare method) Tonsillectomy Versus Coblation Tonsillectomy with regards to Intraoperative Time, Intraoperative blood Loss, Post-Operative Pain and early return to normalcy.

Objective:

Prospective study to systemically analyze the advantages of conventional (Dissection and snare method) Tonsillectomy Versus Coblation Tonsillectomy with regards to Intraoperative Time, Intraoperative Blood Loss and Post-Operative Pain and outcomes

MATERIALS AND METHODS

Inclusion criteria

Chronic tonsillitis

Recurrent tonsillitis (more than 5-6 episodes/year.)

Patients in the age group of 12-50 years.

Exclusion criteria:

Age less than 12 years

Acute infections

Adenoid hypertrophy

Bleeding and clotting disorders

Cervical spine pathology**...**

Chronic sinusitis

Patients on anticoagulant therapy and oral contraceptives

Uncontrolled hypertension, diabetes mellitus and bronchial asthma

Severe malnutrition

Immunodeficiency status like HIV and patients on steroids and chemotherapy

STUDY DESIGN

It is a prospective cohort study analyzing 50 patients who were divided into 2 groups each group comprising of 25 patients.

Group I were analysed with regards to **conventional tonsillectomy** with **group II** who underwent **coblation tonsillectomy** based on **peroperative bleeding, per operative time ,post operative pain,** and **return to normalcy.**

Every patients were admitted on day1, under went basic blood investigations including complete blood count, renal function test, **bleeding time**, **clotting time**, urine routine, X-ray soft tissue skull ,**Diagnostic nasal endoscopy** to rule out adenoids, HIV, VDRL and With prior pre operative anesthetic assessment.

Every patients on the day of operation were given **pre operative antibiotics** and underwent surgery under General anesthesia.

On the table per operative time and amount of bleeding were noted.post operatively all patients were put under **I.V. antibiotics on 1st day** and oral antibiotics from next day for subsequent 3 days. Post operative pain (visual analogue scale), early diet intake, and return to normalcy were recorded into statistical data.

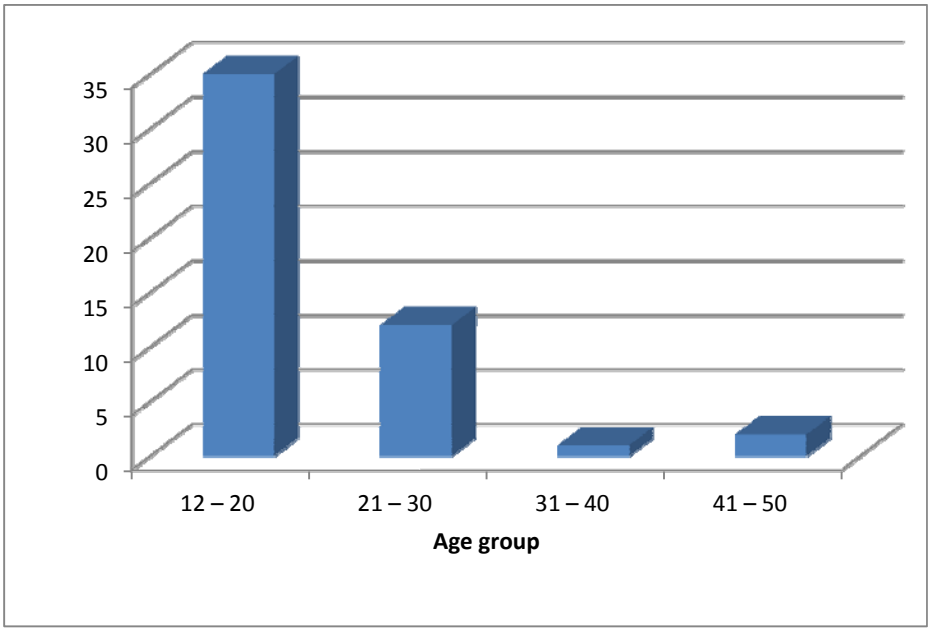
Key words: Tonsillectomy, Coblation tonsillectomy, Radiofrequency, Conventional tonsillectomy.

STUDY AND RESULTS

In this study 50 patients were selected and divded into two groups – each group consisting of 25 patients arranged randomly using lot system. **Group I** go for conventional and **group II** go for coblation tonsillectomy.

Table 1: **AGE GROUP DISTRIBUTION**

Age (years)	Number	Percentage
12 – 20	35	70
21 – 30	12	24
31 – 40	1	2
41 – 50	2	4
Total	50	100



Among the age distribution **35** patients were under **20**years of age contributing to **70%** of total study group.

The next highest age group was between **21 to 30 years** contributing **24%** of the total study group.

Among the gender wise distribution of the 50 patients in this study group, **33** were male contributing **66%** and **17** were female contributing to **34%** of the total study group.

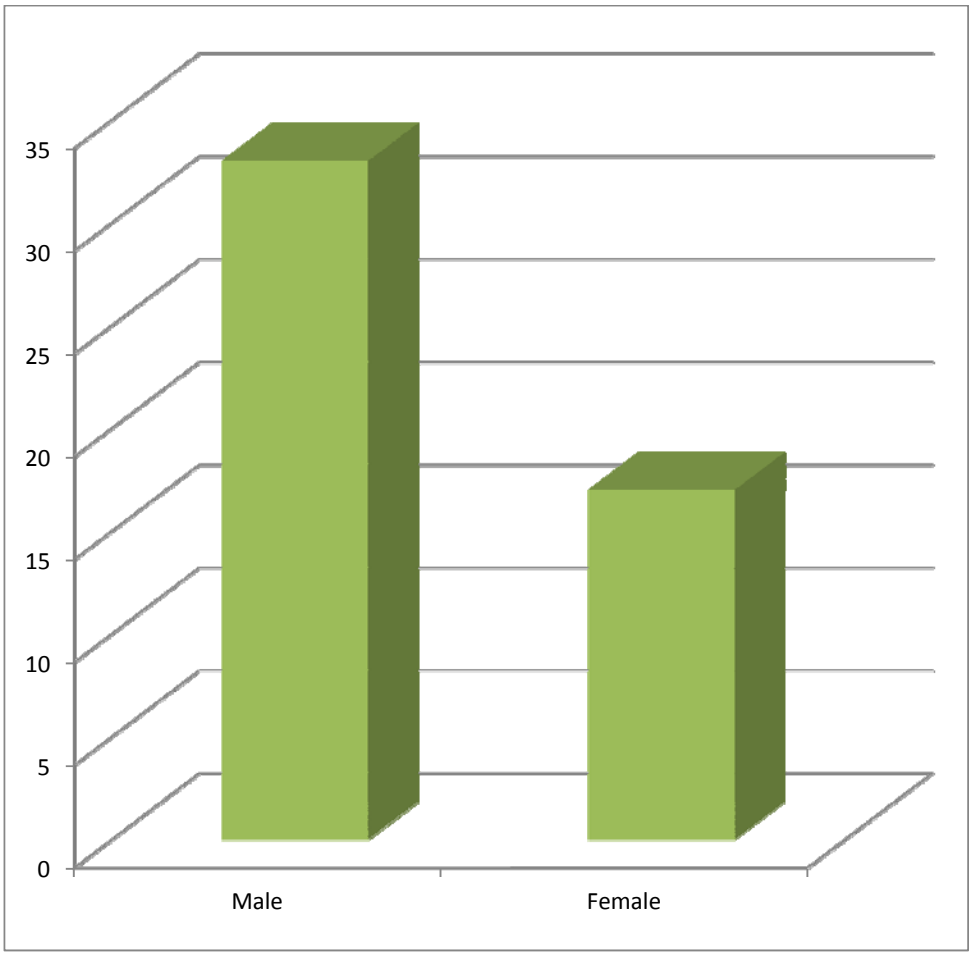
In this study age group between **31 to 40** had only one patient contributing to just **2 %** and between age group **41 to 50** had only **2** patients contributing to **4%** of the total. The bulk of the patients belonged to age group **12 to 20** showing reduced incidence of chronic tonsillitis with the advancing age.

Specimens of post tonsillectomy were also sent for **histopathological** examination for all the cases.

All the results with histopathological examination showed features of **chronic tonsillitis** only thereby avoiding bias in this study.

Table 2 : GENDER WISE DISTRIBUTION

Gender	Number	Percentage
Male	33	66
Female	17	34
Total	50	100



Among the gender wise distributon of the total study group of 50 patients 33 patients were male and 17 patients were female.

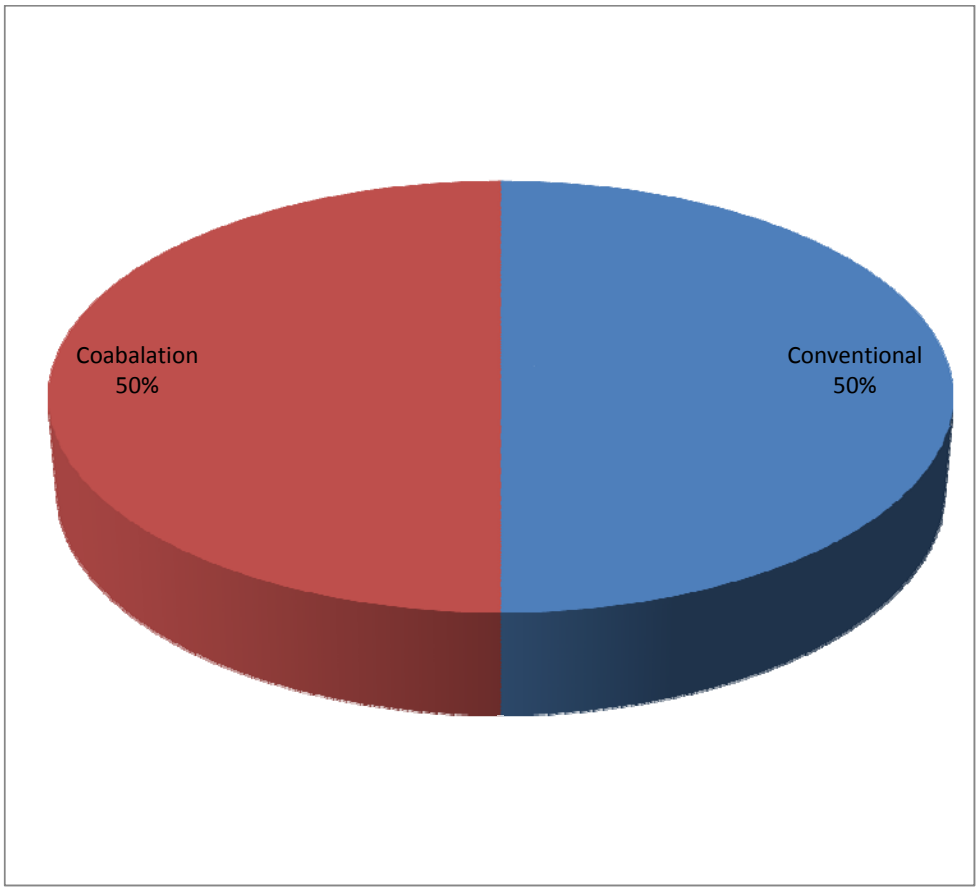
The percentage wise distribution was **66%** for males and only **34%** were females.

This gender wise distribution shows the common occurrence of chronic tonsillitis being more in males than females.

Table 3: STUDY SUBJECTS DISTRIBUTION

ACCORDING TO SURGERY

Surgery	Number	Percentage
Conventional	25	50
Coabalation	25	50
Total	50	100

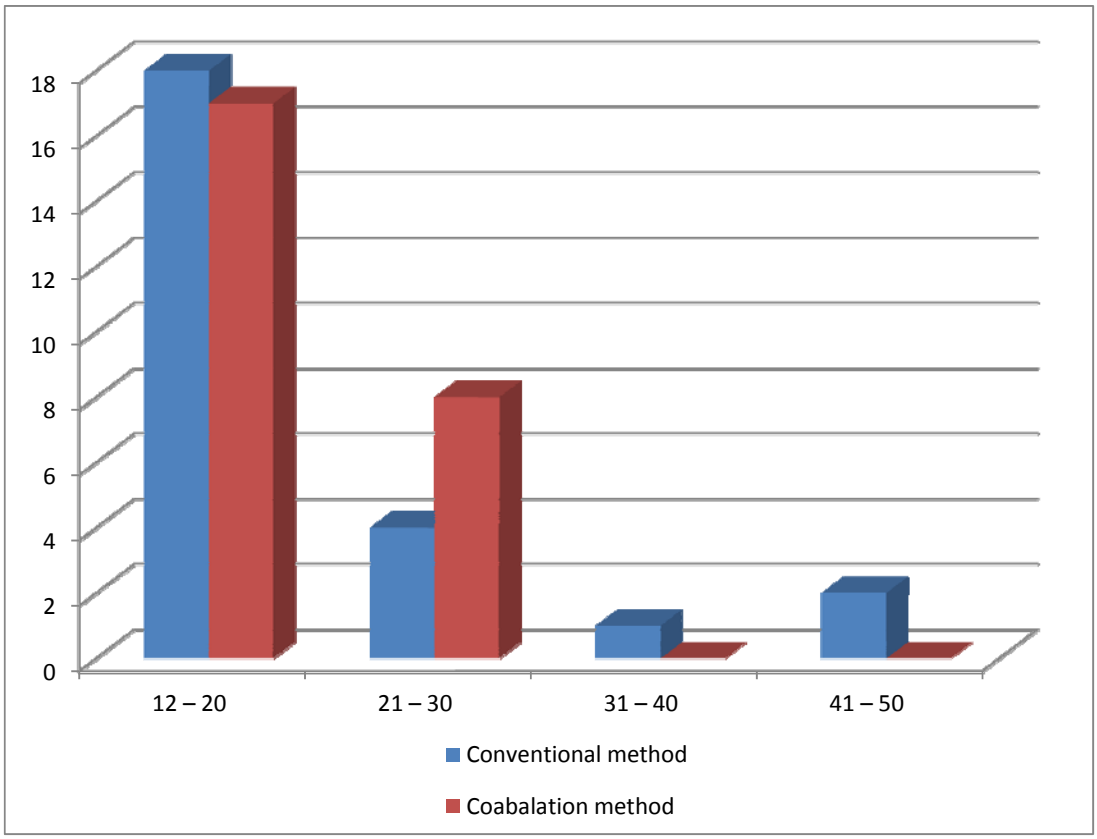


This picture shows equal distribution of patients in **GROUP I AND GROUP II.**

According to surgery wise distribution, **50%** were under conventional group and **50%**were under coblation group so that 25 cases were in group I, under conventional Tonsillectomy and 25 cases were grouped in group II, under Coblation Tonsillectomy.

Table 4: **AGE WISE DISTRIBUTION ACCORDING TO SURGERY**

Age (years)	Conventional method (%)	Coabalation method (%)
11 – 20	18 (72)	17 (68)
21 – 30	4 (16)	8 (32)
31 – 40	1 (4)	-
41 – 50	2 (8)	-
Total	25 (100)	25 (100)



SURGERY WISE DISTRIBUTION - AGE GROUP

Among the surgery wise distribution of the age group almost **72%** were in the age group of **12 to 20 years** in the conventional group and **68%**were in the coblation group.

In the age group **21 to 30,** four patients were included in the study contributing to **16%** in the group I and **8** patients were included in the group II contributing to **32%** of the total.

In the age group of **31 to 40**, one patient was included in the group I contributing to **4%** of the total and no patients were included in the group II.

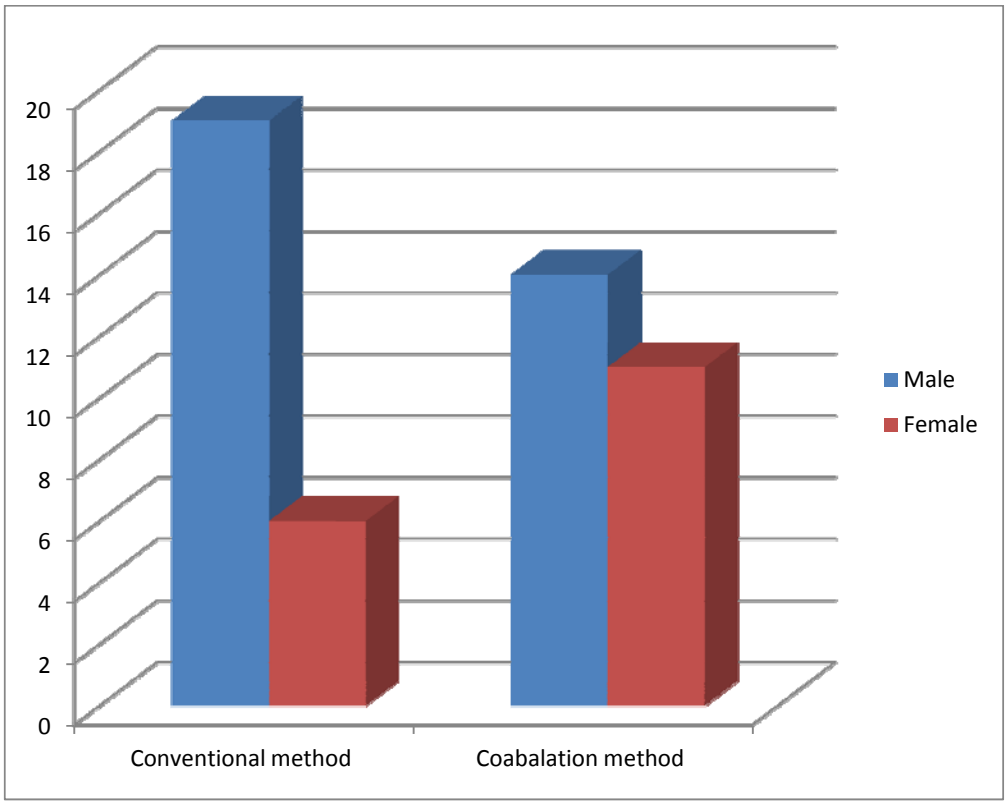
In the group **41 to 50**, two patients was included in the group I contributing to **8%** of the total and no patients were included in the group II.

So this age wise distribution with regards to surgery shows almost **70%** were within the age group of **11 to 20** indicating the commonest occurrence of chronic tonsillitis between the above mentioned age group.

Table 5: GENDER WISE DISTRIBUTION

ACCORDING TO SURGERY

Gender	Conventional method (%)	Coabalation method (%)
Male	19(76)	14(56)
Female	6	11
Total	25 (100)	25 (100)



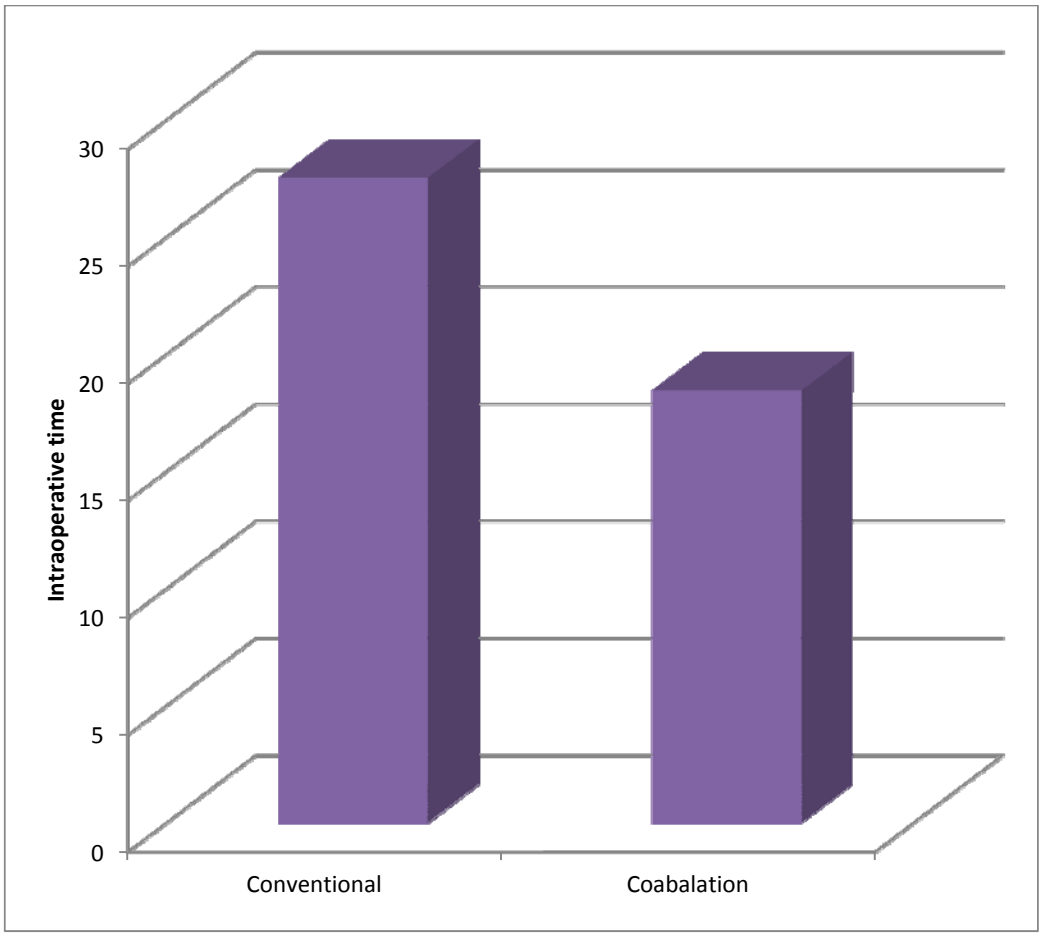
The above results shows almost 19 patients were male in the conventional group contributing to 76% and 6 were females contributing to 24% of the total patient.

In the group II 14 patients were male contributing to 56% and 11 were females contributing to 44% of the total.

The above results shows majority of the patients who underwent surgery were males both in group I and group II.

Table 6: INTRAOPERATIVE TIME FOR CONVENTIONAL TONSILLECTOMY VERSUS COBLATION TONSILLECTOMY

Procedure	Range (mins)	Mean (SE)	T stat	P Value
Conventional	20 – 35	27.52 (± 0.62)	9.694	0.0001
Coabalation	14 – 27	18.44 (± 0.70)		



INTRAOPERATIVE TIME

Among the intra operative time between conventional and coblation tonsillectomy the range was between **20 to 35 minutes** in the group I and **14to 27 minutes** in the group II

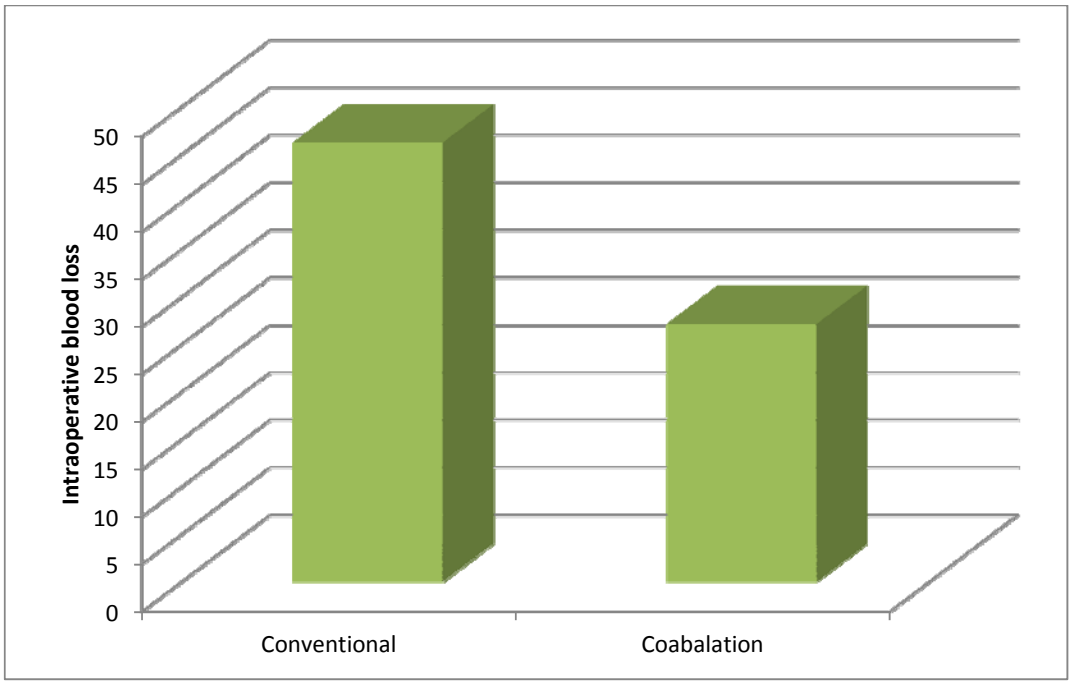
Mean range was **27.52 (±.62**) for conventional and **18. 44 (±.70)** for the coblation with the T stat of 9.694

The above results shows the lesser range of time for coblation tonsillectomy with an even lesser mean value showing lesser intraoperative time and early return to normalcy with a lesser intraoperative anaesthetic complication with coblation tonsillectomy

INTRA OPERATIVE BLOOD LOSS

Table 7: Intraoperative estimated blood loss for conventional tonsillectomy versus coabalation tonsillectomy

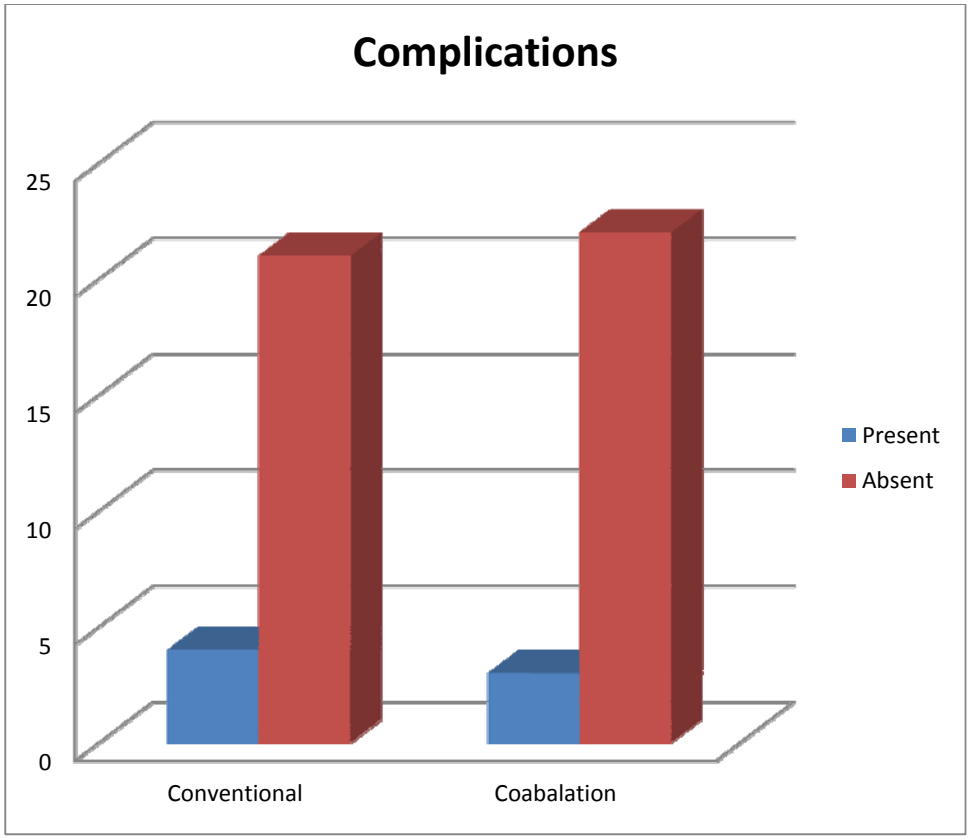
Procedure	Range (ml)	Mean (SE)	T stat	P Value
Conventional	35.5 – 62.5	46.27 (± 7.6)	10.653	0.0001
Coabalation	20 – 39	27.17 (± 4.8)		



Among the intra operative blood loss, for conventional tonsillectomy it was in the range of **35.5** to **62.5** with mean of **46.27** and for coblation tonsillectomy it was in the range of **20 to 39** with the mean of **27.17. T stat value 10.653 and P value 0.0001.**

Table 8: Occurrence of complication in the study groups

Procedure	Complications	
	Present	Absent
Conventional	4	21
Coblation	3	22



Occurrence of Complications

Commonest complications encountered during the surgery were per operative hemorrhage, including **reactionary hemorrhage, post operative pain, delay in swallowing, Post operative fever, tonsillar remnants etc**.

In our study we encountered seven complications one patient in group I had reactionary hemorrhage which was controlled with adequate care with ligation of bleeding point using bipolar cauterization under general anesthesia.

Two patients had minimal tonsillar remnants both of them belong to group I Postoperative pain was the most common complication encountered in the study

In the **group I** - one patient had severe and persistent post operative pain which was treated with intramuscular and oral analgesics.

In the **group II** - 3 patients had persistent post operative pain in the third day which was treated with intramuscular and oral analgesics.

The post operative pain in group II was due to tissue fibrosis without scarring which may be one of the important problems that may be encountered with coblation tonsillectomy.

The post operative pain encountered during coblation tonsillectomy was readily treated with intramuscular and oral analgesics only.

SEVERITY OF PAIN

Severity of pain was assessed using **visual analogue scale** (VAS) and the results showed the following.

The visual analogue score was a objective score using patients words categorizing in to **mild (0-4), moderate (5-8) and severe (9,10).**

In the first post operative period nine patients in the group II encounterd mild pain and nil in group I

20 patients in group I had moderate pain and 15 patients in group II encountered moderate pain with **chi square value of 12.38** with a **P value of 0.002**.

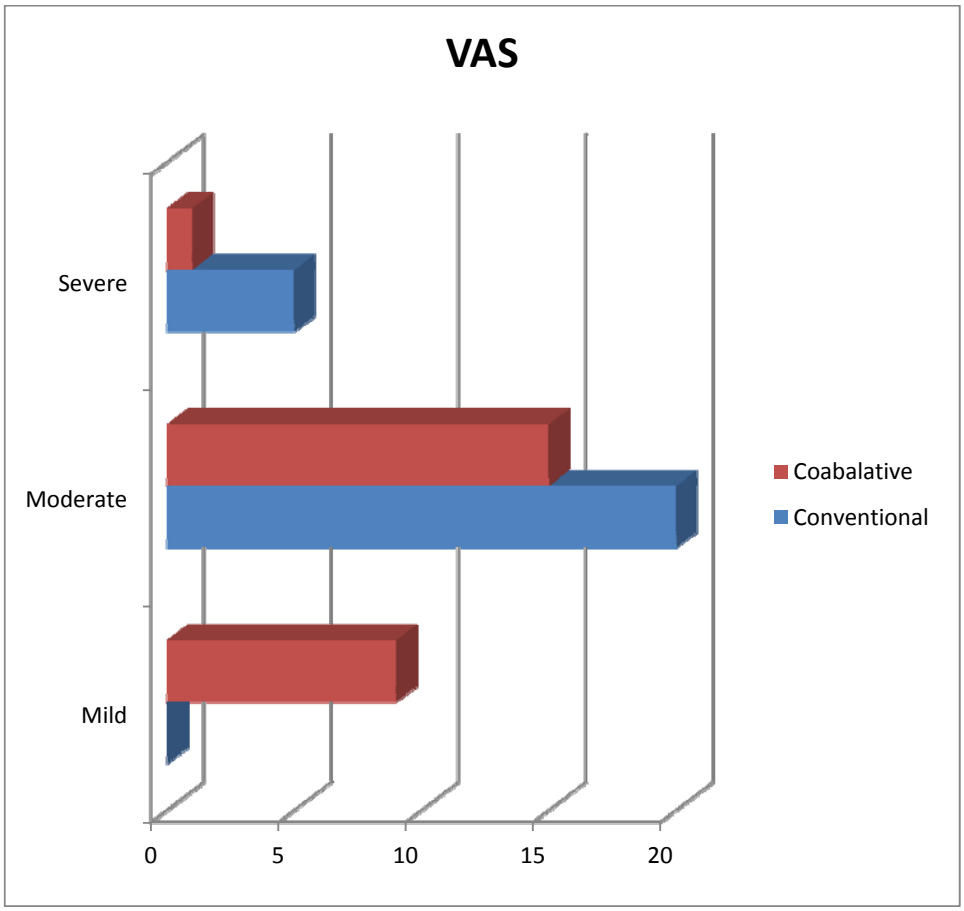
5 patients in group I had severe pain and only **one patient** had severe pain on day one in the group II

The above results showed lesser occurrence of severe pain on day 1 in group II

Table 9: Severity of pain in the postoperative period among the study groups

1st Post operative day

VAS	Group I	Group II	Chi square	P value
Mild	0	9		
Moderate	20	15	12.38	0.002
Severe	5	1		



In group I, **20** patients had moderate pain, no patients had mild pain, **5** patients having severe pain.

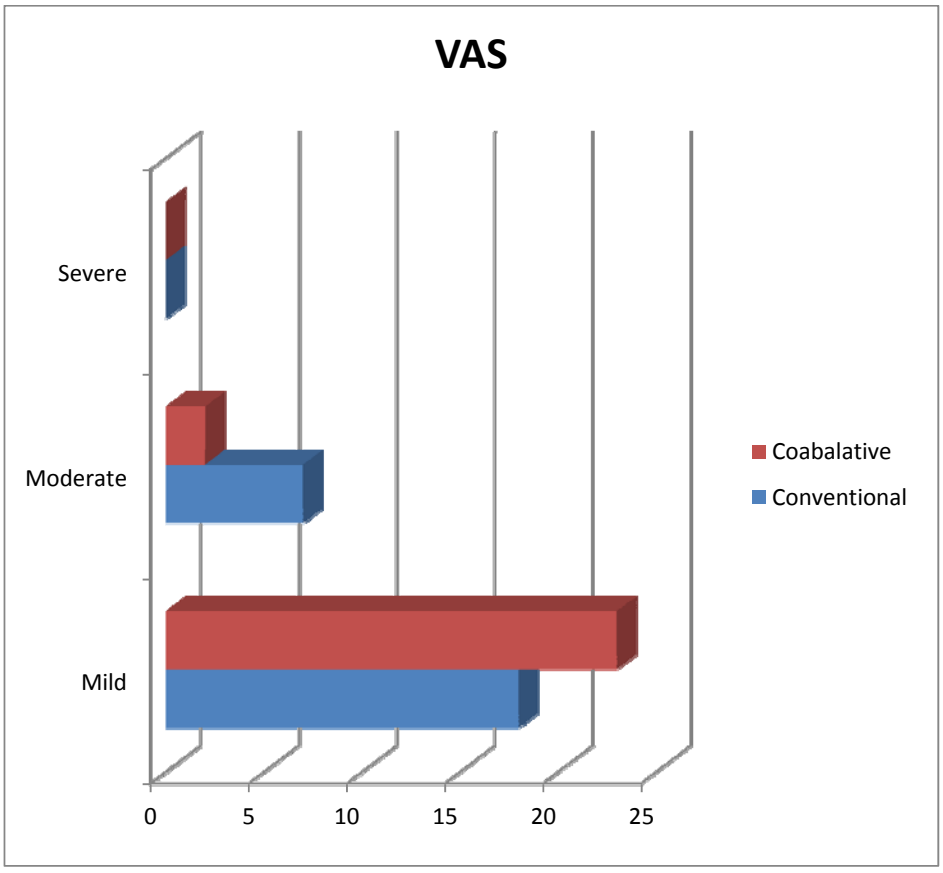
In group II,**9** patients having mild pain, **15** patients had moderate pain, **1** patients had severe pain.

Chi square starts 12.38 and **p** valve **0.002.**

The above results shows in compare to group I and group II, group I 5 patients had severe pain and one patient had severe pain.

2nd Post operative day

VAS	Group I	Group II	Chi square	P value
Mild	18	23		
Moderate	7	2	3.39	0.069
Severe	-	-		



In the second post operative day **18 patients** had mild pain in the group I and **23 patients** had mild pain in the group II

7 patients had moderate pain in group I and 2 patients had moderate pain in group II on second postoperative day with **chi square value 3.39 and P value of 0.69.** No patient had severe pain in both the groups on the second postoperative day.

The above results shows most of the patients had only mild pain during second post operative pain and only nine of them encountered severe pain on the 2 post operative day and none had severe pain.

3rd Post operative day

In the 3rd Post operative day 25 patients encountered mild postoperative pain in the group II and 4 patients encountered mild pain in the group I

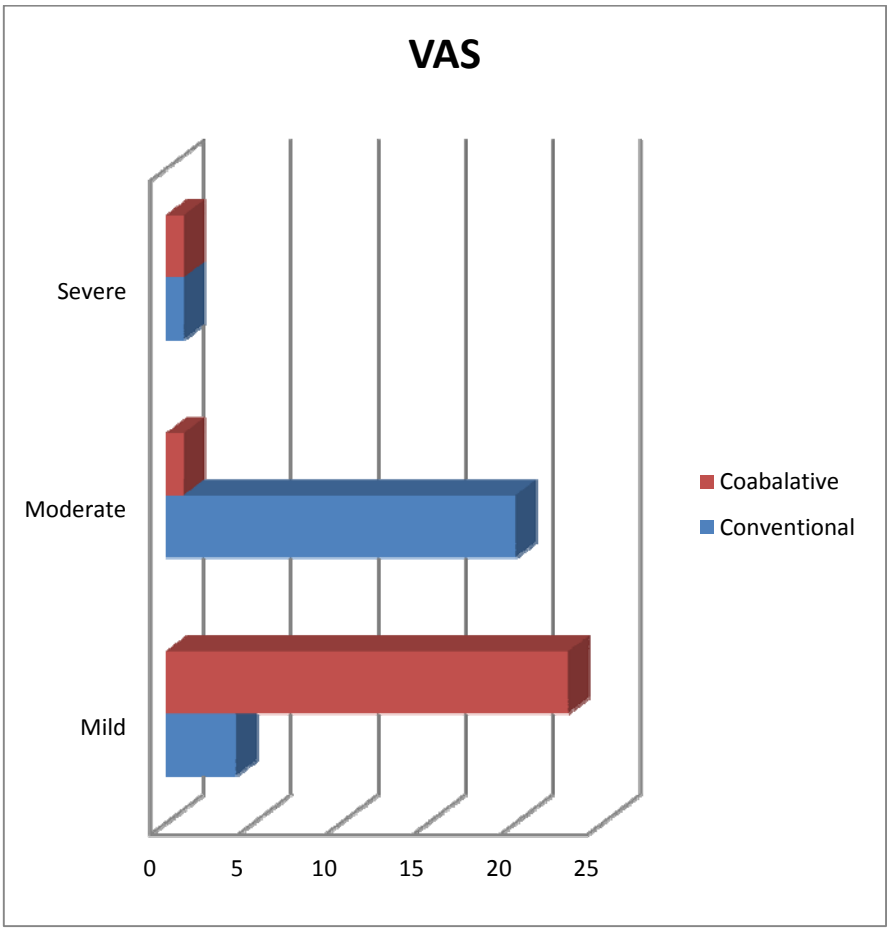
20 patients in the group I had moderate pain and **one had** severe pain in the 3rd post operative day with **chi square value 30.56 and P value of 0.0001.**

In the group II one of patients had both moderate pain and severe pain

This above results shows moderate to severe pain in the group II than with group I indicating better tolerance and **superiority** of coblation over conventional method.

Table 10: Change in severity of pain in post operative days in Conventional procedure group

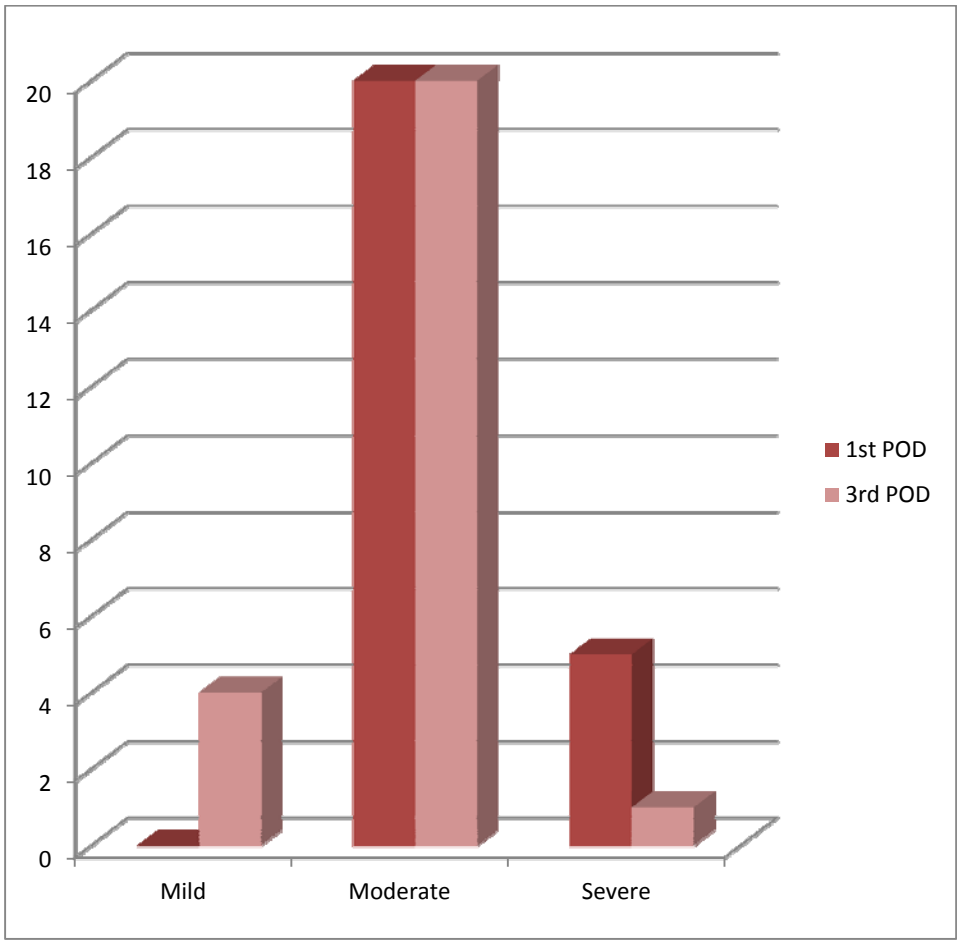
VAS	Conventional	Coabalative	Chi square	P value
Mild	4	23		
Moderate	20	1	30.56	0.0001
Severe	1	1		



Severity of pain in post operative days in

Conventional procedure group

VAS	1st POD	3rd POD	Chi square	P value
Mild	0	4		
Moderate	20	20	6.67	0.035
Severe	5	1		



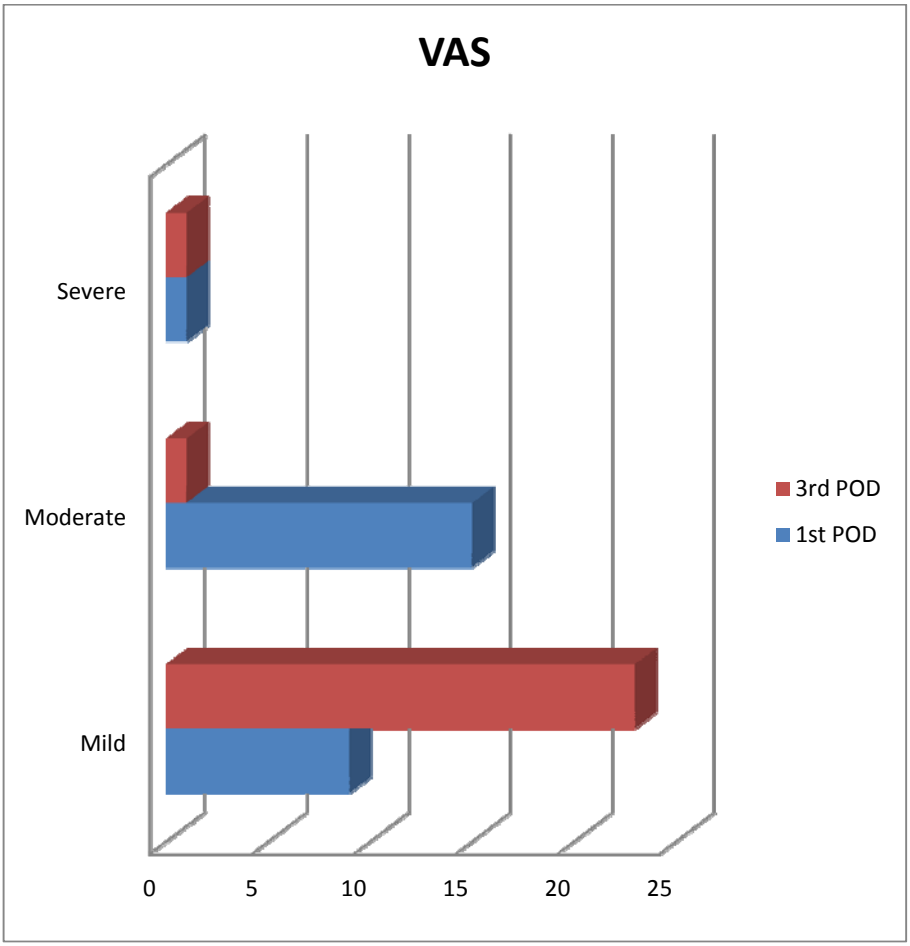
4 patients had mild pain in 3rd post operative day, **20 patients** had moderate pain 1st post operative day, 20 patients in 3rd post operative day.

Among 5 patients had severe pain in 1st post operative day, one patient had severe pain in 3rd post operative day.

That shows **chisqure valve** of **6.67 p** valve shows **0.035**

Table 11: Change procedure group in severity of pain in post operative days in Coabalative

VAS	1st POD	3rd POD	Chi square	P value
Mild	9	23		
Moderate	15	1	18.38	0.0001
Severe	1	1		



Severity of pain in post operative days in Coabalative method

Nine patients had mild pain in 1st post operative day

23 patients had mild pain in 3rd post operative day

15 patients had moderate pain in 1st post operative day

One patient had moderate pain in 1st post operative day

One patient had severe pain in 1st post operative day

One patient had severe pain in 3rd post operative day

Chi squre chart shows 18.38

P valve of 0.0001.

DISCUSSION

Coblation tonsillectomy is still considered to be one of the newer technique among tonsillectomy procedures and noted to be the bridge between **cold and hot** methods. This study was performed to compare the intraoperative efficiency

Though the age group and gender groups are almost similar in both groups the results compared with records to the following criteria showed variable yielding.

Among the complications compared, expect for the post operative pain coblation method seem superior in all aspects with regards to per operative time, intra operative bleeding, early swallowing, lesser stay in the hospital and less complication. The only complication encountered in this study with coblation is post operative pain in the 3rd and subsequent post operative days the reason for which may be due to surgical fibrosis with coblation method. But the mean average pain score was less in group II in our study. With the other criteria's coblation definitely had an edge over conventional tonsillectomy.

Our Study Comparesion with other studies

Name of the study	Total number of patients	mean Operative time in group I and group II	Mean intraoperative bleeding in group I and group II	Outcome
Silvola etal-2011	80	30min vs 15 min	18 ml vs 11 ml	Lesser pain, early discharge , Lesser intraoperative bleeding with coblation
Lee etal - 2008	48	25 min vs 17.9 min	27 ml vs 20 ml	Lesser peroperative complications,early return to normalcy were better with coblation
Sezen etal-2008	125	21.5min vs 36.44 min	32.4ml vs 17.28ml	Early Return to normalcy lesser postoperative morbidity with coblation method.Postoperative pain was equal in both the groups.

Our Study Comparesion with other studies

Name of the study	Total number of patients	Mean Operative time in group I and group II	Mean intraoperative bleeding in group I and group II	Outcome
Karatzias etal-2006	81	22.67 min vs 22.23 min	16 ml vs no measurable bleeding	Mean return to normalcy, peroperative complications lesser with coblation
Stavroulaki etal-2007	32	21 min vs 14.5 min	58ml vs 9.4 ml	Better Tonsillar fossa healing and lesser nausea and vomiting in coblation
Our study	50	27.2min vs 18.44 min	46.27 ml vs 27.17 ml	Better tonsillar fossa healing, lesser operative time ,less amount of peroperative bleeding,early return of normal activities

In our study group II (coblation) shows better tonsillar fossa healing, lesser operative time, less amount of preoperative bleeding, early return of normal activities.

Comparative pain by visual analogue scale, coblation was **superior** to conventional method.But study variation depends on tolerance of the individual.

With Postoperative early return of normal activities, coblation is **superior** to conventional method.

In the study by **silvola etal-2011**, 80 patients were included and divided into equal groups for whom the average intraoperative time was 30 min for convential and 15 min for coblation and post operative bleeding was 14 ml for conventional and 11 ml for conventional in comparison with our study mean **average time duration almost equal** but the per operative bleeding in both groups was found to be **lesser.**

In the study **lee etal-2008,** 48 patients were included in the study group the mean average intraoperative time was 25 min for the group I and 17.9 for group II which was almost comparable with our study the average intraoperative bleeding was 27 ml for

group I and 20 ml for group II which was found to be **lesser** than our study.

In the study **sezen etal-2008**, 125 patients were included in the group with a mean average intraoperative time of 36.4 min for group I and 21.5 min for group II which on comparison our study was found to be **better average introperative bleeding** was 32.4 ml for group I and 17.28 ml for group II which was **comparable** with our study

In the study by **karatzius etal-2006** ,81 patients were included with mean operative time of 22.67min in group I vs 22.23 min in group II which is **comparable** with our study the mean intra operative bleeding of 16 ml in the conventional method and no measurable bleeding in group II which was **better** than in our study.

In the study by **stavroulaki etal-2007**,32 patients were included with mean operative time of 21min in group I and 14.5 min in group II which was **comparable** with our study the mean intraoperative bleeding of 58 ml in group I and 9.4 ml in group II which was **better** than in our study.

So on comparing the above study with our study showed **better per operative bleeding, intraoperative bleeding ,return to normalcy and the average pain by visual analogue score** which is an objective score was found to be **superior** in coblation method than conventional method.

CONCLUSION

With the above study following above conclusion were obtained

- Peroperative time consumption and intra operative bleeding were very **minimal** with coblation method than with the conventional method.
- Post operatively early swallowing and lesser hospital stay were other **advantages** of coblation method over conventional method.
- Post operative pain using symptomatic and visual analogue score was **less** in with the coblation than conventional method of tonsillectomy.
- **Cost effectiveness**, surgical skills, **steep learning curve** and **microscopical settings** were three main **disadvantages** with the coblation method.
- **Coblation method** was found to be **SUPERIOR to conventional method** using systemic criteria based **prospective analysis.**

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Group I

S.NO	Name	Type of surgery	Age	Sex	Duration (mins)	blood loss(ml)	1	2	3	Stay (days)	Compli-cation
1	Praveen kumar	1	19	m	30	45	2	1	1	3	Nil
2	Augustin	1	13	m	27	50.5	2	1	1	3	Nil
3	Divya	1	18	m	25	52.5	2	2	1	3	Nil
4	Divya Dharshini	1	17	f	25	47.5	3	1	3	3	Nil
5	Veera Lakshmi	1	26	f	27	45.6	2	1	1	3	Nil
6	Ramya	1	15	m	28	47.5	2	2	1	3	Nil
7	Pauadas	1	47	m	20	42.5	2	1	2	3	Nil
8	Zinith	1	13	m	25	48.5	2	1	2	3	Nil
9	Sreekanth	1	18	m	25	39.5	2	1	1	3	remnant tonsil
10	Hemanth	1	15	m	30	48.5	2	1	1	3	Nil
11	Srihari	1	24	m	27	54.5	2	1	2	3	pain
12	Elisa Anbu	1	16	m	25	62.5	3	2	2	3	Nil
13	Dinesh	1	11	m	30	59.6	2	1	1	3	Nil
14	Manasa	1	19	f	30	60.5	2	2	2	3	remnant tonsil
15	Rithika	1	13	f	26	35.5	3	2	1	3	Nil
16	Mahni	1	30	f	30	38.5	2	1	1	3	Nil
17	Dhinesh	1	13	m	32	42.5	2	1	2	3	Nil
18	Pavithra	1	18	f	35	45.5	2	1	1	3	Nil
19	Dhanush kumar	1	14	m	25	36.5	2	1	1	3	Nil
20	Periyaswamy	1	14	m	27	47.5	2	1	2	3	reactionary haemorrhage
21	Jaya kumar	1	15	m	28	49.5	3	2	2	3	Nil
22	Harris polachal	1	12	m	28	35.5	3	1	1	3	Nil
23	Jacob polachal	1	14	m	26	38.5	2	2	1	3	Nil
24	Shanmugam	1	29	m	25	40.5	2	1	1	3	Nil
25	Riyana	1	18	f	32	42	2	1	2	3	Nil

Group II

S.No	Name	Type of surgery	Age	Sex	Duration (mins)	blood loss(ml)	1	2	3	Stay (days)	Compli-cation
1	saranya	2	13	f	14	22.3	2	1	1	3	Nil
2	Leo	2	19	m	15	20	2	1	1	3	Nil
3	Vara lakshmi	2	13	f	18	24	1	1	1	3	Nil
4	venilla	2	25	f	17	23	1	1	1	3	Nil
5	Ramya	2	16	f	20	25	2	1	1	3	Nil
6	Jeeva	2	24	m	24	27	2	1	3	3	3th day pain
7	Ramesh	2	22	m	27	29	1	1	1	3	Nil
8	Kaviyarasan	2	24	m	19	30	2	1	1	3	Nil
9	Vasanthi	2	23	m	18	31	2	1	1	3	Nil
10	Vengatesh	2	17	m	15	32	1	2	1	3	Nil
11	Bhuvaneshwari	2	13	f	14	25	1	1	1	3	reactionary haemorrhage
12	Naveen	2	14	m	19	20	2	1	1	3	Nil
13	Aishya	2	22	f	24	24	1	1	1	3	Nil
14	Divyadharshani	2	17	f	18	26	2	1	1	3	Nil
15	Vasmiya	2	20	f	19	29	3	2	1	3	Nil
16	Harsha vardhan	2	12	M	15	35	2	1	1	3	Nil
17	Yasmin	2	17	F	14	30	2	1	1	3	Nil
18	Velayudhan	2	45	M	20	22	1	1	1	3	Nil
19	Harish khan	2	13	M	23	26	2	1	1	3	Nil
20	Divyashanth	2	17	M	15	31	2	1	1	3	Nil
21	Ceshar	2	18	M	15	34	2	1	1	3	Nil
22	Vignesh	2	15	M	20	28	1	1	1	3	Nil
23	Vasudev	2	35	m	21	22	1	1	1	3	3th day fever, pain
24	Rajesh	2	27	m	18	39	2	1	1	3	Nil
25	Anjali	2	30	f	19	25	2	1	1	3	Nil

Case Summary / Pre Operative Questionnaire:-

Name:- Age/Sex:- Occupation:- OP/IP No:-

History:- Contact No:-

Diagnosis; Group ;

1. DURATION OF SURGERY; MINS

2. VOLUME OF INTRA OPERATIVE BLOOD LOSS;

Weight of cotton balls in grams (Volume of blood) =

Volume of blood collected in suction apparatus =

Total blood loss =

3.POST OPERATIVE PAIN

Mild -VAS 0-4

Moderate -VAS4-8

Severe -VAS8-10

4.DURATION OF HOSPITAL STAY FOLLOWING SURGICAL INTERVENTION; 3 DAYS

5. POST OPERATIVE COMPLICATIONS :

INDEX FOR MASTER CHART

Group I –conventional tonsillectomy

Group II-coblation tonsillectomy

H/O-history of

P/O-past history

BT-bleeding time

CT-clotting time

CBC-complete blood count

TC-total count

DC-differential count

Hb%-hemoglobin in grams

ESR- erythrocyte sedimentation rate

RFA-radiofrequency ablation

ASO – Anti steotolysin-o

VSA-visual analogue scale

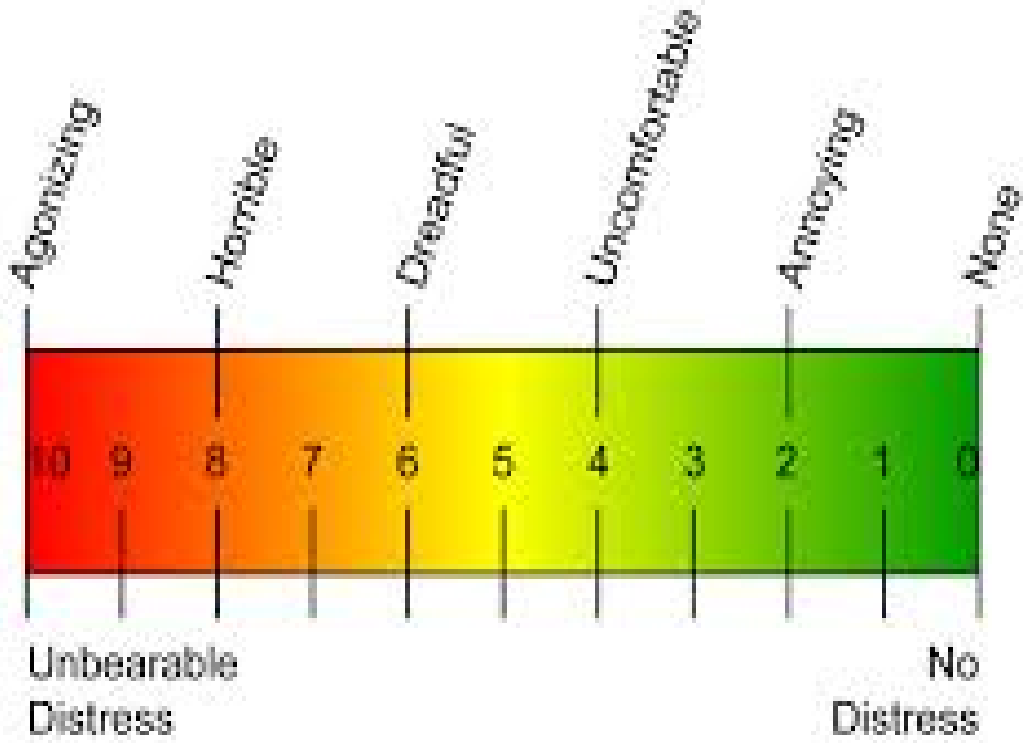
IOT-intraoperative time

IOB-intraoperative bleeding

POD-post operative day

DNE-diagnostic nasal endoscopy

Visual analogue scale



Task _____

Date _____ *Start* _____ *End* _____

ஆராய்ச்சி தகவல் மற்றும் ஒப்புதல் படிவம்

ஆராய்ச்சியாளர் பெயர் : **மரு. அ. பாலகிருஷ்ணன்**

பங்குகொள்பவரின் பெயர் :

இடம் : **அரசு கீழ்ப்பாக்கம் மருத்துவமனை**
சென்னை

ஆராய்ச்சியின் நோக்கம்

எங்கள் மருத்துவமணையில் 12 வயதிலிருந்து 50 வயதுவரை (காது, மூக்கு மற்றும் தொண்டை பகுதியில்) தொண்டையில் சதை வளர்ச்சியில் (TONSIL) பாதிக்கப் படுபவர்களுக்கு இருவேறு அறுவை சிகிச்சை (TONSILLECTEMY) செய்ய உள்ளோம்.

1. எப்பொழுதும்போல் வெட்டி எடுத்தல் முறை (Dissection & Snare)

2. நவீன கருவி (Coablation) மூலம் எடுத்தல்

இரு முறையில் உள்ளவர்கள், குழுக்கள் முறையில் மருத்துவ பரிசோதனைக்கு பிறகு அறுவைசிகிச்சை செய்யப்படுவார்கள்.

அறுவை சிகிச்சைக்கு பிறகு வலியின் தன்மையை அறியவும், அதற்கு பிறகு ஏற்படும் பக்கவிளைவுகளும் நோயாளிகளிடமிருந்து கணத்தில் எடுத்துக்கொள்ளப்படும்.

இதனால் தங்களது சிகிச்சை முறைக்கு எந்தவிதமான பாதிப்புகளும் ஏற்படாது என்றும், இதற்காக எந்த புதிய மருத்துகளும் தங்களுக்கு பரிசோதனை மூலம் வழங்கப்பட மாட்டாது என்றும் உறுதியளிக்கிறோம்.

இந்த ஆய்வின் முடிவுகள் ஆராய்ச்சியின்போது (அ) ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம் /

நாள் : _____ இடது கைரேகை